IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

Sitafia Langston, Tammy Pappelis, Danielle Carpenter, Misty Roxanne Isennock, Alexandra Bunner, Madel Hernandez, Tiffany D. Cook, Megan Oleszczuk, Erika R. Rodriguez, Amy L. Hill, LaQueesha M. Jennings, Isla Lyssette Ramirez, Cynthia Carol Mains, Jessica Mowafy-Francis, TraVivra Arbabe, Cynthia N. Lorenza, Kandice P. Hill, Melissa Bergs, Alecia M. Nauman, Nicole DeMauro, WaKeshia Hughes, , Janet M. Chessor, Dawn Renee Smith, Shontavia K. Williams, Hope L. Lopez, Marando E. Acy, Racheal Lynn Bollmeyer, Jenene J. Hatchard, Tina M. Bacorn, Diana Via, Jennifer Rodrigues, Patricia Mendez, Perla P. Jimenez, LeeAnn Ferrell, TynekMinay Lenora Williams, Shanna Higgs-Latham, Brandy Minder, Cathy Leigh Rademacher, Marisa A. Vieira, Melissa Bloomfield, Mary Garza, Christine Bond, Elizabeth Goodwin, Angela C. Brink, Nicola M. Byrd-Holliday, Samantha Cain, Nieves Hernandez, Catherine L. Terry, Tiffani Bell, Jennifer Rupp, Shauna D. Yazzie, Candy Lynn Claudio, Julley L Meyer, Tyhisha Hudson, Renee Lynn Atkins, Nichole Short, Beth A. Park, Jennifer C. Bennion, Tabitha Harris-Graham, Lisa M. Wallace, Kimberly S. Holland, Nicole Amber McAleese, Emilie R. Smith, Dawn Seaney, Mariola Genge, Crystal Trautman, Anna M Dukes, La'Toya Jones, Shelly Marie Scott, Raquel B. Flores, Ann Marie Smith, Christena Smith, Misty Jo Gibson, Olivia M. Robinson, Michelle Chavez, Helen Pauline Huxford, Lisa Marie Bundy, Katherine Barnett, Harley Hernandez, Tracey D. Koontz, Tracey Peterson, Victoria D. Lawson, Breeanna D. Jackson, Sheba M. Whitiker, Marcy Senica, Terry Williams, Cecilia Salas, Kristina Pitts, Jhonancy Francois, Stacie Calixte, Tahina Smith, Danielle Congleton, and Takesha Dublin, Plaintiffs, vs. BAYER CORP.;BAYER HEALTHCARE LLC; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.);BAYER HEALTHCARE PHARMACEUTICALS, INC.,	)	**Case NO.4:17-cv-01991-JAR** **JURY TRIAL DEMANDED**

Defendants.)
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FIRST AMENDED COMPLAINT

COME NOW the above-named Plaintiffs, subject to their Motion to Remand, by and through their undersigned attorneys, and for their First Amended Complaint against Defendants BAYER CORP., BAYER HEALTHCARE LLC, BAYER ESSURE®, INC. (F/K/A CONCEPTUS, INC.), and BAYER HEALTHCARE PHARMACEUTICALS, INC, (hereinafter collectively referred to as "Bayer Defendants" or "Bayer" or "Defendants"), state as follows:

INTRODUCTION

1. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer; the manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

2. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the healthcare community and to consumers. The manufacturer also must carefully monitor its own manufacturing operations and quality controls to ensure that the device uniformly conforms to the manufacturer-approved design, as well as its representations and warranties and with specifications of approval.

3. When monitoring and reporting adverse events as required by both federal regulations and state law, including Missouri law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to the manufacturer and the medical community that a public safety problem exists. If a manufacturer waits to report post-market information, even for a few weeks or months, that bottleneck could cause researchers, regulatory bodies, and the medical community to be years behind in identifying a public safety issue associated with the device. In the meantime, more patients are harmed by using the product without understanding its true risks. This is why a manufacturer must not only completely and accurately monitor, investigate and report

post-market experience, but it must also report the data as soon as it is received.

4. This action arises from Defendants' failures of their post-market responsibilities to monitor and warn about serious health risks that emerged after their permanent birth control device, Essure®, began to be sold in the United States. In 2002, the U.S. Food and Drug Administration ("FDA") approved the device for sale in the United States based on clinical studies of only 745 women presented by the device manufacturer. When the FDA approved the device, the FDA was not aware that the device could cause serious health risks, such as perforation of the uterus, device migration or fracture, chronic pain, and prolonged bleeding, as well as ectopic pregnancies.

5. After the FDA approved the device for sale and it began to be implanted in patients in a real world setting, Defendants became aware of serious adverse events that should have led Defendants to: (a) directly inform healthcare providers and consumers of these risks by revising the warning label for the device; and (b) report the adverse events to the FDA. For example, Defendants failed to warn health care providers and consumers about roughly 16,000 complaints of serious injuries associated with Essure® after the device was approved for sale. Defendants also failed to timely report this new information to the FDA, which, upon evaluating the information, required a black box warning to reflect serious health risks that were ultimately suffered by Plaintiffs. If the Defendants had timely and adequately warned Plaintiffs' health care providers and Plaintiffs of this new risk information, Plaintiffs' injuries would have been avoided.

6. Not only did Defendants fail to warn about Essure®'s serious health risks, they concealed quality control problems that plagued their manufacturing process and led to material flaws in the devices, which caused device failures in many patients. Despite all of this, Defendants persisted in conducting a nationwide false and misleading marketing campaign. They represented that Essure® was safer than other methods of permanent birth control; Essure® "eliminates the risks, discomfort and recovery time associated with surgical procedures;" Essure® devices "stay secure, forming a long protective barrier against pregnancy;" Essure® is "worry free," and "it's the most effective permanent birth control by far." In Defendants' words, their marketing strategy aimed to capitalize on a physicians' position of trust with patients.

7. The conduct of Defendants violated their obligations under relevant federal and state law,

including Missouri law, governing the post-market conduct of Class III medical device manufacturers.

PARTIES, JURISDICTION AND VENUE

8. The Court has personal jurisdiction over Defendants. Defendant Bayer Essure® Inc. (f/k/a Conceptus, Inc.) and Bayer HealthCare LLC have at all relevant times maintained their corporate headquarters in, and purposefully availed themselves of the benefits, profits and privileges deriving from their business activities in, this state.

9. The Court has personal jurisdiction over the Defendants pursuant to Section 506.500 of the Missouri Revised Statutes because at all relevant times they have engaged in substantial business activities in the State of Missouri. At all relevant times the Defendants transacted, solicited, and conducted business in Missouri through their employees, agents, and/or sales representatives. And there is no federal subject matter jurisdiction because there is no federal question raised and no diversity jurisdiction.

10. There is "specific" personal jurisdiction, because Defendants used St. Louis, Missouri, to develop, create a marketing strategy for, label, or work on the regulatory approval, for Essure®, and *all* of the Plaintiffs' claims arise out of or relate to the Defendants' contacts with Missouri.

11. There is an affiliation between Missouri and the underlying controversy alleged in this Complaint, principally, activities and/or occurrences that took place in Missouri, and the Defendants are therefore subject to Missouri's regulation.

a. Defendants engaged in extensive contacts with Missouri during the development of Essure®, creating a marketing strategy for Essure®, creating the Essure® labeling, and in obtaining FDA approval of Essure®.

b. St. Louis, Missouri was a site of the studies that allowed Conceptus—Defendants' predecessor-in-interest—to clear Essure® for marketing with the FDA and thereafter to continue marketing the product with inadequate labeling because of a failure to follow-up during post-marketing testing.

c. Conceptus was required to conduct four pre-approval clinical studies for Essure®'s initial pre-market approval ("PMA") submission to the FDA. To the best of Plaintiffs'

knowledge, for three of those four pre-market clinical studies for Essure®, Conceptus used Missouri hospitals and contracted with Missouri physicians to serve as clinical investigators.[1] Specifically, Conceptus chose Missouri to conduct: **(1) Phase 1A/STOP 01—**STOP Device[2] Placement Feasibility Study Using Hysteroscopy Visualization ("STOP 01 Study"); (2) **Phase 1B/STOP 06**–Evaluation of the Safety and Principles of Operations of the Selective Tubal Occlusion Procedure (STOP) Device in Women Who Are Scheduled To Undergo A Hysterectomy ("STOP 06 Study"); and (3) **Phase III Pivotal (STOP 2000)**—Phase III Study – A Multi-Center Clinical Trial to Demonstrate the Safety and Effectiveness of the STOP Device in Providing Permanent Contraception (hereafter "Pivotal Study").[3]

d. To conduct the **STOP 01** and **STOP 06** studies, Conceptus contracted with Richard Gimpelson, M.D., clinical professor at the St. Louis University School of Medicine, Department of Obstetrics and Gynecology, and staff at, among others, St. John's Mercy Medical Center in St. Louis, Missouri and St. Luke's Hospital, Chesterfield, Missouri, to serve as the Co-Principal investigator.[4] According to the FDA's review of Essure®, it was the **STOP 01** and **STOP 06** studies that were used to support the feasibility and mechanism of action of the Essure® device—"[t]hese studies, which included 99 and 63 patients for

[1] Pursuant to 21 CFR 812.43(a), it was Conceptus' responsibility as sponsor, to select the clinical investigators who are "qualified by training and experience" to investigate the device. Conceptus was also required to maintain control over its investigational materials and monitor the study in accordance with 21 CRF 812.46. The study investigator uses his or her patient population to screen study participation, is responsible for patient enrollment and patient medical care, and more importantly, is responsible for the assessment, recording and reporting of adverse events. See 21 CFR 812.3 (4)(i); 21 CFR 812.100; 21 CRF 812.110; 21 CRF 812.140

[2] During the pre-market stages of Essure®, the device was named and/or referred to as the "STOP Device."

[3] *See* ESSURE System for Permanent Birth Control Executive Summary, available at: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463460.pdf.

[4] See Dr. Gimpelson's CV, available at: http://webcache.googleusercontent.com/search?q=cache:kgzZ492SnLkJ:www.mdnetlink.com/gimpelson/rjgvitae.doc+&cd=4&hl=en&ct=clnk&gl=es.

perihysterectomy and pre-hysterectomy studies, respectively, yielded data on device placement, patient comfort, as well as histological data to support the mechanism of action of the device."[5]

e. With respect to the Pivotal Study, Conceptus contracted with Dr. David Levine at St. Luke's Hospital in Chesterfield, Missouri to be the principal investigator.[6] The purpose of the Pivotal Trial was to demonstrate the safety and effectiveness of the Essure® device in providing permanent contraception.[7] Chesterfield, Missouri is **one of only eight** principal sites in the United States to perform the Pivotal Trial.[8] That Pivotal Trial took place between May 2000 and February 2001 in Missouri, and was **one of two** pre-market clinical trials Conceptus was required to perform before Essure® could obtain FDA approval.

f. Conceptus included the results from these clinical studies in its PMA submission to the FDA in April of 2002 and was later granted FDA approval to begin marketing and selling Essure® in November of 2002.[9]

g. The information gained from the Essure® Pivotal Trial also formed the basis for safety and efficacy data in the FDA approved Essure® Instructions for Use ("IFU").[10] At the time of

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[5] See "FDA Review Document: Review of the Essure System for Hysteroscopic Sterilization," prepared for the September 24, 2014 meeting of the Obstetrics and Gynecology Devices Advisory Panel, available at: https://www.fda.gov/downloads/AdvisoryCommittees/UCM463486.pdf.

[6] See "Microinsert Nonincisional Hysteroscopic Sterilization", available online at: http://journals.lww.com/greenjournal/Fulltext/2003/07000/Microinsert_Nonincisional_Hysteroscopic.14. aspx.

[7] See Essure Professional Labeling (2002) at pp. 12-17, available online at: https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014c.pdf.

[8] See Jay M. Cooper, et al., Microinsert Nonincisional Hysteroscopic Sterilizationn, 102 ACOG G.J. 59, 59-60 (July 2003), also available online at: http://journals.lww.com/greenjournal/Fulltext/2003/07000/Microinsert_Nonincisional_Hysteroscopic.14. aspx (last visited Mar. 28, 2017).

[9] See Conceptus, Inc. 2002 Form 10-k, available at: https://www.sec.gov/Archives/edgar/data/896778/000095016803001146/d10k.htm.

[10] See ESSURE System for Permanent Birth Control Executive Summary, available online at: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463460.pdf (last visited Mar. 28, 2017).

approval, Essure® was Conceptus' only product, and **Conceptus chose St. Louis, Missouri as ground zero**—it was the first city in the United States to commercially offer the Essure® procedure, which was performed by Dr. Levine.[11]

h. One of the two post-approval studies mandated by the FDA was performed in part in Missouri. The post-approval study performed in part in Missouri—P020014/PAS002—required that patients from the Pivotal Study be followed for five years in order to assess the long-term safety and effectiveness of Essure®.[12] However, Defendants failed to adequately follow-up on the Missouri trial subjects from the P020014/PAS002 study. Had the post-approval study performed in Missouri been adequate and follow-up been competently performed, the true (and highly alarming) safety profile of Essure® would have been made known to Plaintiffs, their physicians, and the public at large, years earlier.

i. The Defendants also engaged in directed marketing and advertising efforts in St. Louis, Missouri, including direct to consumer and direct to physician marketing. The Defendants specifically targeted St. Louis, Missouri, as one of eight cities that were part of a broader marketing plan to increase sales and revenue.[13] St. Louis was key to Defendants' national marketing plan.

j. Defendants engaged Key Opinion Leaders ("KOL") in Missouri to promote Essure®. For example, Dr. Levine served as a KOL. Dr. Levine was a peer reviewer for the articles that

[11] See "St. Louis women among first to try new birth control procedure", November 15, 2002, available online at: http://www.semissourian.com/story/93623.html.

[12] See Regulatory History, available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm; see also https://www.ncbi.nlm.nih.gov/pubmed/25917278.

[13] "**We advertise in eight cities** that have been selected based on a hurdle rate penetration of in-office physicians, adequate reimbursement and sales support, and the ability to extrapolate appropriately to predict national results related to various submarket attributes." See https://seekingalpha.com/article/106240-conceptus-inc-q3-2008-earnings-call-transcript?page=5 (emphasis added).

positively portrayed Essure®,[14] promoted Essure® in publications,[15] trained other physicians on the procedure,[16] was used in press releases by Conceptus regarding Essure®,[17] and authored a number of white papers discussing the benefits of Essure® as they relate to physician credentialing and re-credentialing.[18]

12. Jurisdiction in this court is proper because the Defendants have conducted continuous business and research activities that are sufficiently related to the nonresident Plaintiffs' suits. Had it not been for the clinical trials and marketing strategy formulated and conducted in St. Louis, Missouri, the nonresident Plaintiffs' in this suit would never have had Essure implanted in their bodies. These studies and marketing strategy were key to the success and promotion of Essure on a nationwide stage. Without the Defendants' actions in St. Louis, Missouri, none of the Plaintiffs herein would have had Essure implanted whether they reside or do not reside in St. Louis, Missouri.

13. Jurisdiction in this court is also proper because the Defendants and their agents committed torts in whole or in part against Plaintiffs in Missouri, including but not limited to negligent and wrongful conduct in connection with the development, testing, promoting, marketing, distribution, labeling and/or sale of Essure®.

14. Venue is proper in this county in accordance with Section 508.010 (4) of the Missouri Revised Statutes because the conduct that gave rise to Plaintiff Sitafia Langston's cause of action occurred in the

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[14] Ballagh, Susan A., "Contraceptive Technology Reports: Sterilization in the Office: The Concept Now is a Reality," February 1, 2003, available online at: https://www.ahcmedia.com/articles/26978contraceptive-technology-reports-sterilization-in-the-office-the-concept-now-is-a-reality

[15] Levine, David J., "Hysteroscopic Sterilization: a Breakthrough in Women's Health, 2003, available online at: http://www.aagl.org/wp-content/uploads/2013/01/NewsScope_Jan-Mar_20031.pdf.

[16] The Associated Press, November 12, 2002, "St. Louisans try new birth control procedure," available online at: http://www.berkeleydailyplanet.com/issue/2002-11-15/article/16137?headline=St.-Louisanstry-new-birth-control-procedure&status=301.

[17] Conceptus, Inc., "New Data Confirms Successful Use of Essure® Permanent Birth Control," November 9, 2005, available online at: http://www.prnewswire.com/news-releases/new-data-confirms-successfuluse-of-essurer-permanent-birth-control-in-an-office-setting-55489802.html.

[18] "Clinical Privilege White Paper: Transcervical sterilization," June, 2006, available online at: http://www.hcpro.com/content/61602.pdf.

City of St. Louis, Missouri, and she was first injured by the wrongful acts and negligent conduct by the Defendants in the City of St. Louis, Missouri. The Plaintiffs are all properly joined in this action pursuant to Section 507.040 of the Missouri Revised Statutes as they assert a right to relief under the same series of occurrences, and questions of law and fact are common to all plaintiffs in this action.

15. Plaintiff Sitafia Langston resides in Saint Louis, MO, St. Louis City.

16. Plaintiff Tammy Pappelis resides in Hastings, MN.

17. Plaintiff Danielle Carpenter resides in Ruther Glen, VA.

18. Plaintiff Misty Roxanne Isennock resides in Chattanooga, TN.

19. Plaintiff Alexandra Bunner resides in Lancaster, PA.

20. Plaintiff Madel Hernandez resides in Lancaster, TX.

21. Plaintiff Tiffany D. Cook resides in Shady Spring, WV.

22. Plaintiff Megan Oleszczuk resides in Wilburton, OK.

23. Plaintiff Erika R. Rodriguez resides in Albuquerque, NM.

24. Plaintiff Amy L. Hill resides in Monette, AR.

25. Plaintiff LaQueesha M. Jennings resides in Wichita, KS.

26. Plaintiff Isla Lyssette Ramirez resides in Houston, TX.

27. Plaintiff Cynthia Carol Mains resides in Falmouth, KY.

28. Plaintiff Jessica Mowafy-Francis resides in Hoxie, AR.

29. Plaintiff TraVivra Arbabe resides in Kalamazoo, MI.

30. Plaintiff Cynthia N. Lorenza resides in Shelby Township, MI.

31. Plaintiff Kandice P. Hill resides in Wimberley, TX.

32. Plaintiff Melissa Bergs resides in Kalamazoo, MI.

33. Plaintiff Alecia M. Nauman resides in Myerstown, PA.

34. Plaintiff Nicole DeMauro resides in Oxford, MA.

35. Plaintiff WaKeshia Hughes resides in Detroit, MI.

36. Plaintiff Janet M. Chessor resides in Ripley, MS.

37. Plaintiff Dawn Renee Smith resides in Liberty, IN.

38. Plaintiff Shontavia K. Williams resides in Desoto, TX.

39. Plaintiff Hope L. Lopez resides in Phoenix, AZ.

40. Plaintiff Marando E. Acy resides in Clovis, NM.

41. Plaintiff Racheal Lynn Bollmeyer resides in Murfreesboro, TN.

42. Plaintiff Jenene J. Hatchard resides in East Orange, NJ.

43. Plaintiff Tina M. Bacorn resides in Durant, IA.

44. Plaintiff Diana Via resides in Stafford, VA.

45. Plaintiff Jennifer Rodrigues resides in Navarre, OH.

46. Plaintiff Patricia Mendez resides in Nederland, TX.

47. Plaintiff Perla P. Jimenez resides in Giddings, TX.

48. Plaintiff LeeAnn Ferrell resides in Mount Vernon, IL.

49. Plaintiff TynekMinay Lenora Williams resides in Pineville, NC.

50. Plaintiff Shanna Higgs-Latham resides in Krum, TX.

51. Plaintiff Brandy Minder resides in Carmi, IL.

52. Plaintiff Cathy Leigh Rademacher resides in Edinburg, TX.

53. Plaintiff Marisa A. Vieira resides in North Providence, RI.

54. Plaintiff Melissa Bloomfield resides in Bucyrus, OH.

55. Plaintiff Mary Garza resides in San Antonio, TX.

56. Plaintiff Christine Bond resides in Salt Lake City, UT.

57. Plaintiff Elizabeth Goodwin resides in Bourbonnais, IL.

58. Plaintiff Angela C. Brink resides in Nunda, NY.

59. Plaintiff Nicola M. Byrd-Holliday resides in Greenville, SC.

60. Plaintiff Samantha Cain resides in Ennis, TX.

61. Plaintiff Nieves Hernandez resides in Chicago, IL.

62. Plaintiff Catherine L. Terry resides in Plano, TX.

63. Plaintiff Tiffani Bell resides in Manchester, NH.

64. Plaintiff Jennifer Rupp resides in Tacoma, WA.

65. Plaintiff Shauna D. Yazzie resides in Flagstaff, AZ.

66. Plaintiff Candy Lynn Claudio resides in Muskegon, MI.

67. Plaintiff Julley L Meyer resides in Hattieville, AR.

68. Plaintiff Tyhisha Hudson resides in Ardmore, PA.

69. Plaintiff Renee Lynn Atkins resides in East Saint Louis, IL.

70. Plaintiff Nichole Short resides in High Point, NC.

71. Plaintiff Beth A. Park resides in Saint Clair, MO.

72. Plaintiff Jennifer C. Bennion resides in Vernal, UT.

73. Plaintiff Tabitha Harris-Graham resides in Lees Summit, MO.

74. Plaintiff Lisa M. Wallace resides in Madison, WI.

75. Plaintiff Kimberly S. Holland resides in New Marshfield, OH.

76. Plaintiff Nicole Amber McAleese resides in Monroe, NC.

77. Plaintiff Emilie R. Smith resides in Jacksonville, NC.

78. Plaintiff Dawn Seaney resides in Paragould, AR.

79. Plaintiff Mariola Genge resides in Orland Park, IL.

80. Plaintiff Crystal Trautman resides in Saint Louis, MO.

81. Plaintiff Anna M Dukes resides in Hesperia, MI.

82. Plaintiff La'Toya Jones resides in Byron, GA.

83. Plaintiff Shelly Marie Scott resides in Whiteland, IN.

84. Plaintiff Raquel B. Flores resides in Ramona, CA.

85. Plaintiff Ann Marie Smith resides in Biloxi, MS.

86. Plaintiff Christena Smith resides in Armada, MI.

87. Plaintiff Misty Jo Gibson resides in Richland, WA.

88. Plaintiff Olivia M. Robinson resides in Springfield, VA.

89. Plaintiff Michelle Chavez resides in Albuquerque, NM.

90. Plaintiff Helen Pauline Huxford resides in Westminster, CA.

91. Plaintiff Lisa Marie Bundy resides in High Ridge, MO.

92. Plaintiff Katherine Barnett resides in Waynesville, MO.

93. Plaintiff Harley Hernandez resides in Mount Vernon, MO.

94. Plaintiff Tracey D. Koontz resides in Kearney, MO.

95. Plaintiff Tracey Peterson resides in Saint Louis, MO.

96. Plaintiff Victoria D. Lawson resides in Chesterfield, MO.

97. Plaintiff Breeanna D. Jackson resides in Arnold, MO.

98. Plaintiff Sheba M. Whitiker resides in Pine Bluff, AR.

99. Plaintiff Marcy Senica resides in Oglesby, IL.

100. Plaintiff Terry Williams resides in Tacoma, WA.

101. Plaintiff Cecilia Salas resides in Pflugerville, TX.

102. Plaintiff Kristina Pitts resides in Kingsbury, TX.

103. Plaintiff Jhonancy Francois resides in Pasadena, TX.

104. Plaintiff Stacie Calixte resides in Brockton, MA.

105. Plaintiff Tahina Smith resides in Angola, IN.

106. Plaintiff Danielle Congleton resides in Parker, CO.

107. Plaintiff Takesha Dublin resides in Rome, GA.

108. Defendant BAYER CORP. is a for-profit corporation incorporated in the state of Indiana and is a wholly owned subsidiary of Bayer A.G. Defendant is authorized to and does business throughout the state of Missouri. BAYER CORP. principal place of business is in Pittsburgh, Pennsylvania.

109. Defendant BAYER HEALTHCARE LLC is a for-profit limited liability company organized under the laws of the state of Delaware with its principal places of business located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205 and 100 Global View Drive, Warrendale, Pennsylvania. BAYER HEALTHECARE LLC's is a wholly owned subsidiary of Bayer A.G. and its sole member is Defendant BAYER CORP. Defendant is authorized to and does business throughout the state of Missouri.

110. Defendant BAYER ESSURE® INC. (F/K/A CONCEPTUS, INC.) is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer A.G. and/or Bayer HealthCare LLC. Conceptus, Inc. ("Conceptus") was founded in 1992 by Julian Nikolchev, a self-described "medical technology developer and serial entrepreneur." On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC. On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly owned subsidiary of Bayer HealthCare LLC and/or Bayer A.G., and thereafter was renamed "Bayer

Essure® Inc." For purposes of this Petition, Conceptus, Inc. and Bayer Essure® Inc. are one and the same. Bayer Essure® Inc.'s headquarters were located at 1021 Howard Avenue, San Carlos, California 94070 until 2005 when they relocated to 331 East Evelyn Avenue, Mountain View, California 94041. In July of 2013, Bayer Essure® Inc. moved its headquarters to 1011 McCarthy Boulevard, Milpitas, Santa Clara County, California 95035. Upon information and belief, as of May 20, 2016, Bayer Essure® Inc. surrendered its right to conduct intra-state business in the state of California and relocated its principal place of business to New Jersey. Defendant is authorized to and does business throughout the state of Missouri.

111. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer A.G. Defendant's principal place of business is in Montville, New Jersey. Defendant is authorized to and does business throughout the state of Missouri.

112. At all times herein mentioned, there existed a unity of interest, and activity in furtherance of that interest, among Defendants such that any individuality and separateness among them has ceased, and these Defendants are the alter egos of each other with respect to Essure® operations.

113. Defendants acted jointly and in combination with one another to take advantage of each Defendants' resources, personnel, services, and sales, marketing and promotional networks in an effort to advance their misleading nationwide marketing scheme for Essure®. This includes the Defendants transacting, soliciting and conducting business in Missouri through their offices, employees, agents and/or sales representatives, from which they derived substantial revenue in Missouri.

114. At all times herein mentioned, Defendants, jointly and individually, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling the Essure® device. These products were for use by the Plaintiffs and Plaintiffs' physicians and were implanted into Plaintiffs in the same condition as when the Essure® devices left Defendants' control. As such, each of the Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

DESCRIPTION OF ESSURE®

115. Essure® is a medical device manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

116. Essure® was first manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Conceptus, Inc. and initially developed under the name Selective Tubal Occlusion Procedure or "STOP™" Permanent Contraception device.

117. Essure® is touted as a form of permanent female birth control (female sterilization) with a 99.74% effectiveness rate of preventing pregnancy. Defendants marketed the device as being safer and more effective than alternative forms of birth control. The device was developed to prevent pregnancy through the insertion of micro-inserts into the fallopian tubes that then expand and anchor, causing fibrous tissue growth and, in turn, bilateral occlusion (blockage) of the fallopian tubes. Defendants intended the device to be implanted "permanently," *i.e.*, for each patient's lifetime.

118. Essure® consists of three components: (1) two micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use.

119. The micro-inserts are composed of two metal coils: one coil made of nitinol (nickel and titanium) and the other made of steel with polyethylene terephthalate ("PET") fibers wound in and around the coil. The micro-inserts are placed in a woman's fallopian tubes via Defendants' disposable delivery system.

120. Defendants' disposable delivery system consists of a single handle that contains a nitinol core delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians monitor this process through hysteroscopic equipment, including a hysteroscope, a lightbox, and a monitor, collectively known as a "tower." Upon information and belief, the towers were valued at approximately $20,000 and were provided by Defendants to physicians for free if the physician purchased twenty-five Essure® units.

121. The hysteroscopic equipment is not part of the Essure® device or its pre-market approval process, but the equipment is necessary for proper implantation of the Essure® device. Defendant Bayer's

website warned physicians, "[i]n order to be trained in Essure® you must be a skilled operative hysteroscopist."

122. After placement of the coils in the fallopian tubes, the micro-inserts are intended to expand and anchor into the fallopian tubes. Defendants claim in their physician training manual and patient information booklets that the expanded coils and a chronic inflammatory and fibrotic response to the PET fibers elicit tissue growth that blocks the fallopian tubes and prevents pregnancy. According to Defendants, "the tissue in-growth into the insert caused by the PET fibers results in both insert retention and pregnancy prevention."

123. In an initial clinical trial of 99 subjects, Conceptus aimed to assess the ability of the inserts to anchor in the fallopian tubes by asking doctors to perform a subjective "tug test." Thus, early on Defendants recognized that correct placement of the device was often a subjective determination.

124. Defendants claim that "correct placement" of Essure® "is performed easily because of the design of the microinsert," and the physician training manuals suggest the system and hysteroscope allow for visual confirmation of each insert's proper placement during the implant procedure. Defendants further claim in advertising materials that the coils will remain securely in place in the fallopian tubes for the life of the patient, claiming, for example, Essure® is a "proven permanent birth control procedure that works with your body to create a natural barrier against pregnancy" and that it is "not reversible."

125. The Instructions for Use ("IFU") accompanying the Essure® device provide that patients should be counseled to receive a confirmation test three months' post-implant to determine that the coil micro-inserts have created a complete occlusion in each fallopian tube. The Confirmation Test is performed using a hysterosalpingogram ("HSG Test") and, as of July 2015, a transvaginal ultrasound ("TVU").

126. Defendants have stated in a publicly available Form 10-K filed with the U.S. Securities and Exchange Commission that HSG is "often painful" and "is also known to be highly inaccurate, with false-positive results in as many as 40% of HSG-diagnosed cases of proximal tubal occlusion ("PTO"). Various factors are believed to be responsible for these false indications of tubal occlusion, including tubal spasm (a natural function of the tubes) and a build-up in the tube of natural cellular debris and mucous." Defendants did not, however, share this information with patients in their marketing materials.

127. Since Essure®'s market entry in 2002, the device has undergone several design changes. The Selective Tubal Occlusion Product ("STOP") device was the original model used in two clinical trials (STOP 10 and STOP2000) submitted in an effort to obtain FDA approval of the device. The first U.S. launched device was the ESS205 model, which was the same inserts as the STOP device, but incorporated a different delivery system (i.e., support catheter). The original support catheter was discontinued because Defendants perceived it as the reason that the inserts were perforating women's fallopian tubes and causing pelvic pain. Additional changes were later made to the delivery system. In 2007, Defendants changed the shape of the inserts by removing the tapered "pigtail" at the proximal end of the outer coil and renamed the device the ESS305 model.

PRE-MARKET APPROVAL OF ESSURE®

128. In April 2002, Conceptus submitted its Premarket Approval (PMA) Application to the FDA for the Essure® device. The PMA Application was based on data derived from feasibility studies conducted in St. Louis, Missouri; and the Pivotal Trial—conducted in Chesterfield, Missouri—to determine safety and effectiveness of Essure®.

129. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices based on the information available at the time. *See* 21 U.S.C. § 360(e); 21 C.F.R. § 814.3(e).

130. Under 21 C.F.R. § 814.20, a PMA and/or PMA Supplement application must provide:

a. proposed indications for use;

b. device description including the manufacturing process;

c. any marketing history;

d. summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e. each of the functional components or ingredients of the device;

f. methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. any other data or information relevant to an evaluation of the safety and effectiveness of

the device known or that should reasonably be known to the manufacturer from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

131. Conceptus was required to summarize the studies conducted in Missouri as part of the PMA application. Further, data from the Pivotal Trial which determined Essure® safety and effectiveness was essential to the PMA. Thus, the data derived from Missouri was directly related to the regulatory approval of Essure® and ultimately, the implantation of Essure into each Plaintiff.

132. On November 4, 2002, the FDA conditionally approved the Essure® PMA application.

133. Because the FDA approval in 2002 was based on studies of only 745 clinical trial patients for a short period of time, Defendants understood at that time that the long-term nature of the human body's tissue response to the Essure® inserts was unknown. The majority of the clinical trial data regarding PET in the fallopian tube was based on only 12–24 months of implantation. Beyond 24 months, therefore, the nature of the body's cellular and fibrotic response to the inserts and the ability of the devices to maintain occlusion were unknown. The FDA advised Conceptus of these facts and emphasized their special significance with respect to the risk of ectopic pregnancies, putting Conceptus on clear notice that the company's duty to vigilantly monitor and report the real world clinical experience with the device was paramount. Thus, the importance of maintaining the integrity of post-marketing data collection and reporting was known to Defendants from the outset.

134. Conceptus falsified the records of patients who participated in clinical trials. For example, Kimberly Hudak was an Essure® clinical trial patient. During her participation in the trial she responded to questions from a Conceptus representative regarding whether she experienced pain, adverse events, or changes to her usual state of health that she attributed to the device. Although Ms. Hudak reported that she experienced unusual pain, the Conceptus representative recorded that she did not.

135. The FDA's Conditional Premarket Approval ("CPMA") Order for Essure® established several requirements for the manufacturer, and the Order expressly made non-compliance with any of these requirements a violation of federal law. For example, the Order required that the manufacturer:

a. conduct a post-approval study in order to gather long-term safety and effectiveness data on Essure®;

b. conduct a post-approval study in the U.S. to "document the bilateral placement rate [of Essure®] for newly trained physicians";

c. annually report on the patients who participated in the post-approval studies;

d. ensure that any warranty statements are truthful, accurate, not misleading and are consistent with applicable federal and state laws;

e. submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification. In the case of a labeling modification under these circumstances, the type of mandatory PMA supplement to be submitted was a "Special PMA Supplement – Changes Being Effected," which allowed the manufacturer to implement its label change without prior FDA approval;

f. submit annual post-approval reports to the FDA including reports of data from any clinical or nonclinical laboratory studies involving the device and reports in the scientific literature concerning the device;

g. submit a report to the FDA within 10 days after Defendants receive or have knowledge or information of any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that has not been addressed by the device's labeling or has been addressed by the device's labeling but is occurring with unexpected severity or frequency. The express purpose of this requirement was to provide continued reasonable assurance of the safety and effectiveness of the device;

h. submit a report to the FDA within 10 days after Defendants receive or have knowledge or information of any failure of the device to meet specifications established in the approved PMA that are not correctable by adjustments or procedures described in the approved labeling;

i. include in the Annual Report a bibliography and summary of information from unpublished reports of data from any clinical investigations or non-clinical laboratory studies involving Essure® as well as reports in the scientific literature concerning Essure®;

j. include in the Annual Report any failures of the device to meet the specifications

established in the approved PMA that were correctable by procedures described in the approved labeling; and

k. "[r]eport to the FDA whenever it received information from any source that reasonably suggested that the device may have caused or contributed to a serious injury".

136. The CPMA Order for Essure® further outlined reporting requirements that Defendants were required to follow under the Medical Device Reporting regulations ("MDR"). Under these requirements, Defendants were required to:

a. report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury; and

b. report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

137. The CPMA Order acknowledged the Defendants' obligation and ability to update safety warnings for Essure® without prior FDA approval by utilizing the "Changes Being Effected" provision in 21 C.F.R. § 814.39(d)(2).

138. The FDA made clear in the CPMA order that "[f]ailure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Act."

DEFENDANTS BREACHED THEIR OBLIGATION TO UPDATE WARNINGS AND REPORT ADVERSE EVENTS

139. Approval of a device through the PMA process signals the beginning, not the end, of a device manufacturer's duties to patients under both federal regulations and established state law, including Missouri law. The FDA's initial approval of a device label amounts to a finding by the FDA that the label is adequate for purposes of gaining initial approval to market the device. It does not represent a finding by the FDA that the label can never be deemed inadequate after approval as new safety information from the real world experience with the device becomes available to the manufacturer. Sound reasons support these principles: there are products, such as Essure®, for which evidence of the device's defects comes to

light only after the device is used in a real world setting.

140. After Essure® received pre-market approval, Defendants were at all times responsible for maintaining the labeling of Essure® in light of the most current risk information obtained from the real world clinical experience with the device. There is no federal requirement that a manufacturer maintain its original warning language in the face of new safety information. Nor does federal law give device manufacturers a right to market their device using the label originally approved by the FDA when new post-market information bearing on the safety of the device comes to light. To the contrary, the FDCA required Defendants not to sell a device that was accompanied by an inadequate warning or had a label that was false or misleading in any respect, 21 U.S.C. § 352(a), (f)(2), because such a deficient warning rendered the device "misbranded" under 21 U.S.C. § 331, as well as the Sherman Food, Drug, and Cosmetic Laws. West's Ann. Cal. Health & Safety Code § 111330.

141. Defendants had the ability under federal law, and the duty under state and federal law, to directly warn healthcare providers and consumers by unilaterally updating the labeling of Essure® to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d) and CPMA Order, Conditions of Approval. The options available to Defendants include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

142. Defendants breached their duties under federal law and state law, including Missouri law, to maintain labeling that: (a) added warnings about the adverse reactions alleged herein for which there was reasonable evidence of a causal association; (b) added instructions for use that would enhance the safe use

of the device; and (c) added descriptions of adverse events to ensure that the labeling was not false or misleading.

143. Defendants post-approval obligations under federal law also included duties to:

a. report to the FDA information suggesting that one of the Manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, and conduct an investigation of each event and evaluate the cause of the event, 21 C.F.R. §§ 803.50, et seq.;

b. monitor the product after pre-market approval and discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 C.F.R. §§ 814, et seq.;

c. submit a PMA Supplement for any change in Manufacturing Site, 21 C.F.R. §§ 814.39, et seq.;

d. establish and maintain quality system requirements to ensure that quality requirements are met, 21 C.F.R. § 820.20, et seq.;

e. establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, 21 C.F.R. §§ 820.30, et seq.;

f. document all Corrective Action and Preventative Actions taken by the Manufacturer to address non-conformance and other internal quality control issues, 21 C.F.R. §§ 820.100, et seq.;

g. establish internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198 and §§ 820.100, et seq.;

h. establish Quality Management System ("QMS") procedures to assess potential causes of non-conforming products and other quality problems, 21 C.F.R. §§ 820.70, et seq. and 21 C.F.R. §§ 820.90, et seq.;

i. report on Post Approval Studies in a timely fashion, 21 C.F.R. §§ 814.80, et seq.; and

j. advertise the device accurately and truthfully, 21 C.F.R. §§ 801, et seq.

144. Had Defendants fulfilled these obligations in a timely fashion, which federal and state law required them to do, Plaintiffs' injuries would not have occurred. Defendants failed to do so.

145. The claims in this case concern Defendants' duties that arose after premarket approval of Essure®, when Defendants learned of new information bearing on the safety of its device. Defendants breached these duties to take reasonable steps to prevent foreseeable and intended risks, including to the Plaintiffs.

146. Under state law, including Missouri law, Defendants had a duty to exercise reasonable care in adequately warning Plaintiffs and/or Plaintiffs' physicians about the dangers of Essure® that were known or knowable to Defendants at the time of distribution. Under both federal and state law, Defendants also have a post-market duty to monitor and report adverse events and risks associated with the device.

147. Despite having knowledge and possession of evidence that showed the use of Essure® was dangerous and likely to place users' health at serious risk, Defendants failed to disclose and warn of the health hazards and risks associated with Essure®. Instead, Defendants marketed, advertised, and promoted Essure® while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of state law, including Missouri law, and FDA regulations.

148. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

149. The FDA publishes the adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm

150. Defendants had a duty under state law, including Missouri law, to exercise reasonable care in

warning Plaintiffs and/or Plaintiffs' physicians about the dangers of Essure® that were known or knowable to Defendants at the time of distribution. Defendants also had an obligation and the ability under federal regulations to maintain labeling that provided adequate warnings about risks and instructions for use; to conduct prompt, accurate and thorough post-market surveillance; to take action to ensure that the device can be used safely in accordance with the instructions; and to ensure that any labeling, warranties, or representations Defendants made were not false or misleading in any respect. Defendants' conduct here failed to meet these federal obligations and violated state law, including Missouri law.

151. Throughout its existence, Conceptus accumulated hundreds of millions of dollars of debt and never achieved profitability.

152. By 2007, Essure® was the only product sold by Conceptus.

153. To protect the Essure® brand within the permanent birth control market, Defendants made a decision to hide their knowledge of serious safety risks from the FDA and public.

154. The FDA's Office of Regulatory Affairs ("ORA") is the lead office for all field activities, including inspections and enforcement. During an inspection, if ORA investigators observe conditions they deem to be objectionable, these observations are required to be listed on an FDA Form 483 when they indicate that an FDA-regulated product may be in violation of FDA requirements.

155. FDA Form 483s typically are discussed with a company's management team at the conclusion of the inspection. The Form 483 is not an all-inclusive list of every possible deviation from law and regulation. There may be other objectionable conditions that exist that are not cited on the FDA Form 483. Companies must take corrective action to address the cited objectionable conditions and any related, non-cited objectionable conditions that exist.

156. On or about December 2010, the FDA conducted a fifteen-day "For Cause" inspection. During the fifteen-day "For Cause" inspection, the FDA noted conditions that it found objectionable and/or constituted violations of the FDCA and related Acts.

157. The FDA Establishment Inspection Report for this inspection was issued on January 6, 2011, and stated the following:

a. "My inspection of the complaint system of Conceptus Inc. found that the firm was not reporting complaints of loose micro-insert coils in the peritoneal or abdomino-pelvic cavity

(*See* FDA483 Observation #2). . . . In some of these cases the micro-insert coil will migrate through the perforation in the tube and will be found on x-ray to be outside the female reproductive tract in the peritoneal cavity. Such cases will be reported as MDR by the firm if the patient is complaining of pain and a second procedure is required to remove the coil. However, the firm will not report such complaints if an abdominal located coil is removed during a laparoscopic tubal ligation performed because of failure of the Essure® procedure."

b. During this inspection, Conceptus gave the FDA inspector "an Excel spreadsheet with all of the complaints opened since Jan. 1, 2008 [and] there were 16,581 complaint[s] from 1/1/08 until 12/6/10 listed. There were 182 MDRs reported in the same time period."

c. Conceptus also gave the FDA inspector a more detailed complaint spreadsheet "that starts at 7/20/2010 and goes to 12/10/2010. That spreadsheet [had] a total of 2,752 complaints."

d. The FDA inspector looked at the complaints for perforation and noted that "none of the perforation complaints were reported as MDRs."

e. A review of the Risk Analysis Design Failure Mode Effects Analysis showed that it referenced perforation as a possible effect of the failure mode of the coil being too stiff, an explanation to how the manufacturing defects caused perforation. But, migration as a failure mode was not addressed.

158. The objectionable conditions were communicated to Conceptus by the FDA via a Form 483 dated January 6, 2011, and included the:

a. failure to submit MDR determinations to the FDA within 30 days for reports of a serious injury involving the Essure® device, including but not limited to two reports of bowel perforation, one report of pain and the Essure® device breaking into pieces immediately following implant, and 41 complaints that involved perforation of the uterus or fallopian tubes;

b. failure to submit MDR's to the FDA within 30 days for reports of a serious injury involving the Essure® device, including but not limited to five reports of the Essure® coils perforating the fallopian tubes and penetrating the peritoneal cavity;

c. failure to submit MDR's to the FDA with reports of perforation with a post-procedural radiograph (HSG or CT) showing a coil in the abdominal or peritoneal cavity;

d. failure to include perforation of the Essure® micro-coil insert into the peritoneal cavity in its Design Failure Mode Effects Analysis (DFMEA) for Essure®, despite having documented at least 508 complaints of perforation involving the Essure® device;

e. failure to submit MDR's to the FDA for reports of the device failing to function as specified in the PMA when it would be likely to cause or contribute to serious injury; and

f. failure to adequately document in a Corrective Action and Preventative Actions ("CAPA") an incident involving Conceptus's contract manufacturer using uncertified material in a validation protocol and failing to follow their own Standard Operating Procedure for control of non-conforming material. Upon information and belief, these failures resulted in manufacturing defects that harmed those implanted, including Plaintiffs.

159. The FDA inspector specifically advised Defendants that any instances of the device migrating to, perforating, or penetrating areas in the body outside of the fallopian tubes constituted a malfunction and should be reported. In response, the Quality Manager at Conceptus told the inspector that he did not consider an Essure® device falling out of the fallopian tube because of a perforation to be a device malfunction.

160. Upon information and belief, just as Defendants were not reporting such instances as MDRs, they were also not analyzing them as failure modes in Design Controls, nor were they performing their post-market obligations to ensure that the Essure® device was safe and effective as manufactured and in accordance with the requirements of the CPMA and FDA Regulations.

161. Conceptus' CEO had direct personal knowledge of the frequency, severity and permanence of the complications and risks associated with the Essure® device. Despite this knowledge, Defendants failed to take necessary action—such as directing the filing of PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs - to advise users of Essure® of the defects and risks described above, violating federal and state law, including Missouri law.

162. Because Defendants failed to timely, completely, or accurately report their knowledge of risks and complications associated with the Essure® device, the public's knowledge of the risks associated with

the Essure® device were seriously hampered and delayed. This endangered patient safety, including Plaintiffs' safety.

163. On May 11, 2011, at the first quarter 2011 earnings call, Conceptus' CEO discussed Defendants' plan to continue to promote Essure® as safe and effective despite the thousands of adverse event reports they had received.

164. He stated, "We intend to increase productivity, grow our physician pipeline, expand Essure® utilization, and drive greater patient adoption through integrated marketing." He again described Essure®'s "superior efficacy, reduced patient trauma, risk and recovery, and lower cost versus tubal ligation" to investors. He did not discuss how Conceptus had been put on notice of their violations of FDA regulations and failed to report serious adverse events to the FDA.

165. On August 4, 2011 at the second quarter earnings call, he further stated that Defendants had a "comprehensive publication plan to keep physicians up to date on information that may impact their use of Essure®." Despite these statements, Defendants continued to underreport adverse events associated with Essure® to the FDA and medical community.

166. Defendants intentionally, willfully, and maliciously concealed and/or suppressed material safety information regarding Essure® in order to increase sales of Essure®, protect the Essure® brand, and increase market share.

167. Defendants received direct financial benefit from their tortious conduct.

168. In May and June 2013, the FDA conducted another inspection that included an evaluation of Defendants' complaint handling and adverse event reporting practices. As part of the inspection process, the FDA requested a complete list of complaints since January 2011. Defendants provided the FDA inspector with a spreadsheet containing 16,047 complaints Conceptus received on the Essure® device between January 2011 and the date of the inspection, only 183 of which were reported by Defendants to the FDA as MDRs.

169. The inspector reviewed 29 random complaint forms received by Defendants. None of the randomly reviewed complaints in which one or more coils were imaged outside of the fallopian tubes were reported to the FDA as MDRs.

170. Upon information and belief, from January 1, 2008 through May 2013, Defendants were

receiving on average over 15 complaints per day about their product and thousands of complaints each year. Defendants timely reported only a tiny fraction of these complaints to the FDA.

171. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus, and FDA Regulations.

172. Defendants had unique knowledge concerning the frequency, severity, and permanence of the complications and risks associated with the Essure® device. Despite this unique knowledge, Defendants failed to take necessary action—such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs—to advise users of Essure® of the defects and risks described above, violating state law, including Missouri law.

173. Defendants' actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Defendants, including, but not limited to, 21 C.F.R. § 814.39(d). Defendants' actions also separately violated parallel duties under state law, including Missouri law, governing their post-marketing conduct.

174. Conceptus also failed to timely submit Post-Approval Studies under the Essure® CPMA. For example, a six-month report was due on August 24, 2012, but was not received by the FDA until December 14, 2012. Other reports were likewise untimely. If Defendants had timely submitted accurate Post-Approval Studies, Plaintiffs and their physicians would have received notice of these complaints.

175. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus, and FDA Regulations, including, but not limited to, 21 C.F.R. §§ 814.80, et seq.

176. By failing to update their labeling as new post-marketing information became available to ensure that its labeling remained both accurate and adequate, Defendants also rendered Essure® a "misbranded" device under the FDCA, which forbid this device from being marketed. These actions also violated parallel state laws governing Defendants' marketing representations and warnings. Despite this, Defendants continued to improperly market Essure® for use in women, including the Plaintiffs, at a time they were prohibited from doing so under federal law. Defendants' actions separately violated duties under state law, including Missouri law, governing their post-marketing conduct.

177. By failing to comply with several CPMA conditions and FDA post-marketing regulations prior

to implantation into Plaintiffs, Essure® was also considered to be an "adulterated" device under § 501(f) of the FDCA and not allowed to be marketed. 21 U.S.C. § 351(h); 21 C.F.R. §§ 814.80, et seq. Despite this, Defendants continued to improperly market Essure® for use in women, including the Plaintiffs, at a time that they were prohibited from doing so under federal law. Defendants' actions separately violated parallel duties under state law, including Missouri law, governing their post-marketing conduct.

178. Defendants' failure to timely file MDR's and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which it knew of from the more than 32,000 complaints that it received, violated the CPMA, FDA post-marketing regulations, and parallel state law. Defendants' violations prevented Plaintiffs, their physicians, and the public from understanding the true nature of Essure®'s adverse events, risks, and ineffectiveness.

179. Defendants' actions violated duties under state law, including Missouri law, governing their post-marketing conduct.

180. Prescribing and implanting physicians, healthcare providers, and patients, including Plaintiffs and their healthcare providers, neither knew, nor had reason to know at the time of their use of Essure®, of the existence of the aforementioned adverse events and defects. Ordinary consumers would not have recognized the potential risks or side effects that Defendants concealed and misrepresented through their promotion of Essure® as safe and effective for pregnancy prevention.

QUALITY PROBLEMS AND MANUFACTURING DEFECTS

181. Defendants had a duty under state law, including Missouri law, to exercise reasonable care in the manufacture, development, marketing, labeling, distributing, and sale of Essure® after it was approved for sale by the FDA in 2002. Defendants also had the obligation and ability under federal regulations to ensure that the product was manufactured utilizing Good Manufacturing Practices and to maintain quality controls to adequately address, investigate, and assess manufacturing issues that arose from the device. Defendants' conduct failed to meet these federal obligations and violated parallel state law, including Missouri law.

182. In June and July 2002, Conceptus did not have a quality control department. Instead, it contracted with an outside entity to periodically audit its manufacturing sites. During that time, the FDA

inspected the Conceptus manufacturing facility in San Carlos, Missouri and issued a Form 483 notice of violation reporting that: (1) design outputs identified as essential for the proper functioning of the device were not completely identified; (2) corrective and preventive action activities had not been documented, including implementation of corrective and preventive actions; (3) the procedures addressing verification or validation of corrective and preventive actions were not implemented; and (4) certain adverse events were not captured in the data submitted for Essure®'s PMA.

183. On June 25, 2002, the FDA conducted a six-day Post Market Approval inspection of the Conceptus San Carlos headquarters and manufacturing facility reviewing procedures, records and processes associated with the four major quality subsystems: Management Controls, Design Controls, Corrective and Preventive Actions, and Product and Process Controls.

184. During the six-day inspection, the FDA issued a Form 483 documenting the following two conditions, which it found objectionable and/or constituted violations of the FDCA and related Acts specific to the quality systems: (1) failure to analyze all quality data sources to identify existing and potential causes of nonconforming product and other quality problems related to the Essure® device; and (2) failure to follow procedures for the control of products that do not conform to specifications. Specifically, raw materials and sub-assemblies (i.e., Inner/Outer Coil Sub-assemblies) were being rejected during manufacturing, but no Material Review Reports were initiated/generated by Conceptus for these rejection. A review of Lot History Reports for the manufacture of Essure® showed raw materials rejected (hand-written) on the Work Order Picklist, but not documented on Quality Assurance Forms, which are used to track data to allow determination of trends in sources of product and quality, such as whether the raw materials and component parts conformed to specifications. Upon information and belief, these failures contributed to manufacturing defects in the products that deviated in material composition and function from the approved design of the product. The use of non-conforming material rendered the affected products defective as manufactured. Upon information and belief, these defects were widespread and impacted many women, including the Plaintiffs. The information concerning the precise scope of defects is uniquely within Defendants' possession and control.

185. Shortly after beginning to manufacture the devices, Conceptus became aware post-market that the following manufacturing defects can occur with the device and lead to adverse consequences for

patients:

a. the stainless steel used in Essure® can become un-passivated, which would allow it to rust and degrade;

b. the nitinol can form nickel-rich phases in the oxide layer during the manufacturing process susceptible to corrosion, allowing *in* vivo corrosion and release of high nickel content, which may trigger adverse immunologic responses;

c. the nitinol coils can fail to achieve the approved design standard flexibility due to the use of non-conforming materials or deviations from the manufacturing process protocol, resulting in coil stiffness that can cause perforation, migration, and pain;

d. the "no lead" solder can contain trace lead;

e. the nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;

f. latent manufacturing defects, such as cracks, scratches, and other disruptions of the smooth surface of the metal coil, could compromise the physical integrity of the inserts, causing fractures, breakage, and excess nickel to leach into the surrounding tissues after implantation;

g. PET fibers degrade at 65 degrees Fahrenheit. Therefore, considerable degradation is expected at 98.6 degrees Fahrenheit in the human body, and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and autoimmune issues;

h. production of non-sterile devices; and

i. the mucosal immune response to nickel and PET fibers, which occurs in the fallopian tubes, has been more severe than the immune response in non-mucosal areas of the body.

186. The devices are not designed to deform, crack, fracture, or break before, during, or after implantation. Yet, Defendants have received notices of each of these types of defects through adverse event reports during the relevant time frame, and Defendants failed to (1) promptly investigate the cause of the manufacturing defects; (2) notify the public that they had occurred; (3) report the adverse events and the manufacturing defects to the FDA; (4) report a failure mode analysis to explain why the

manufacturing defects occurred; and (5) report a corrective action plan to ensure that the manufacturing defects would not reoccur. All of these failures led to continued manufacturing defects and omissions of material information that in turn led to personal injuries in patients, including Plaintiffs.

187. Upon obtaining knowledge of these device failure modes, Defendants were required under the Essure® CPMA, 21 C.F.R. §§ 820.30, et seq., 21 C.F.R. §§ 820.100, et seq. and the FDA Recognized Consensus Standard ISO 14971 to use this information to routinely update the risk analyses for the Essure® device and take any and all CAPAs necessary to address non-conformance and other internal quality control issues. Furthermore, Defendants were required to establish QMS procedures to assess potential causes of non-conforming products and other quality problems with the product, such as latent manufacturing defects. 21 C.F.R. §§ 820.70, et seq.; 21 C.F.R. §§ 820.30, et seq. Lastly, Defendants were required to take necessary action – such as filing PMA Supplements, unilaterally updating their labeling through the CBE Process, and/or timely submitting MDRs – to advise users of Essure® of the defects and risks described above. Defendants failed to comply with these FDA regulations and its parallel duties under state law, including Missouri law, thereby jeopardizing the health of patients.

188. Upon information and belief, Defendants' failure to establish QMS procedures to assess potential causes of non-conforming products, their failure modes in patients, and other quality problems with the Essure® devices resulted in the use of non-conforming materials with manufacturing defects that resulted in migration, perforation, breakage and pain. Upon information and belief, these failures lead to manufacturing defects and patient injuries that were systematic, ongoing, and long-term.

189. Within a year of receiving the FDA's notice of violation concerning the non-conforming devices and inadequate quality controls, Conceptus ceased manufacturing the devices itself and began engaging a foreign contract manufacturer. That did not eliminate the manufacturing defects, however.

190. On March 24, 2004, Conceptus filed an express good manufacturing practice ("GMP") Supplement for the addition of a manufacturing site located at Venusa, Ltd. in Chihuahua, Mexico that was approved by the FDA on April 8, 2004. At that time, Conceptus transferred all of its manufacturing to the Chihuahua, Mexico site.

191. In September 2005, the FDA conducted a pre-announced inspection of the San Carlos headquarters. During the inspection, only two of the four subsystems reviewed in the 2003 inspection

were covered: (1) Corrective and Preventive Actions; and (2) Management Controls. The FDA inspector noted in the Establishment Inspection Report under the Manufacturing/Design Operations section that, in 2004, Conceptus relocated all manufacturing and no longer manufactured the product on-site; however, the finished product went through quality control inspection and quality assurance testing at the San Carlos facility. Product and Process Controls were not investigated by the FDA during this investigation, but the FDA investigator noted "an ongoing issue with deployment/disengagement failure of the Essure® device tracing the issue back to . . . 4/8/2002."

192. On November 7, 2005, Conceptus entered into a three-year supply agreement with Accellent Corp., f/k/a Venusa, Ltd. to manufacture Essure® at its facility in Juarez, Mexico. It did not file the requisite PMA Supplement to advise the FDA of this manufacturing site, in violation of its post-marketing duties under 21 C.F.R. § 814.39. This failure to notify the FDA resulted in Conceptus avoiding inspection of the facility and its manufacturing process for nearly two years.

193. Although Conceptus had transferred all manufacturing in 2004 to Chihuahua, Mexico, it was not until June 25, 2007 that Conceptus sought approval from the FDA for a manufacturing site change from Conceptus, Inc. in Mountain View, California to its contract manufacturer, Accellent Corp., in Chihuahua, Mexico.

194. On June 10 and 11, 2008, the California Department of Public Health, Medical Device Safety Section ("CDPH") conducted an inspection of Defendants' 331 East Evelyn Avenue location in Mountain View, California. During this inspection, the CDPH issued a Notice of Violation to Conceptus for: (1) failing to obtain a valid license to manufacture medical devices after Conceptus moved from its previous location; and (2) failing to maintain its procedure for inventory transfer.

195. In 2011, the FDA cited Conceptus for not developing a corrective plan when it learned that its contract manufacturer had been producing non-conforming devices since at least November 30, 2010. The Conceptus engineers also learned that the contract manufacturer had failed to follow its own standard operating procedures for control of non-conforming material.

196. According to the FDA Inspection Classification Database Search, Accellent Inc. d/b/a Lake Region Medical Inc. in Juarez, Mexico was not inspected until August 7, 2014, when Conceptus was again issued a Form 483 after the FDA again found objectionable conditions or practices.

197. On June 9, 2015, the FDA approved a manufacturing site located at Bayer Healthcare SRL in Heredia, Costa Rica, and the facility was officially opened on August 27, 2015.

198. This conduct by Defendants violated the conditions of the Essure® CPMA and good manufacturing processes. For example, the CPMA required Defendants to notify the FDA when device failures necessitated a manufacturing or device modification, as well as when any chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications occurred. Defendants' conduct invalidated the CPMA and violated parallel state laws governing the post-marketing conduct by Conceptus. In addition, this conduct violated FDA regulations including, but not limited to, 21 C.F.R. § 814.39, 21 C.F.R. §§ 820.70, et seq., as well as the Sherman Food, Drug and Cosmetic Laws, West's Ann. Cal. Health & Safety Code § 111295.

199. Upon information and belief, Defendants' failure to establish and maintain procedures to ensure that the Essure® device, as manufactured, conformed to its approved product specifications – particularly related to non-conforming material and the inadequate quality assurance and failure mode analysis – is well documented and resulted in manufacturing defects causing harm to many women, including Plaintiffs. Upon information and belief, these failures were ongoing and systematic, resulting in manufacturing defects in the product.

DEFENDANTS ENGAGED IN FALSE AND MISLEADING SALES AND MARKETING TACTICS

200. Defendants violated the Essure® CPMA and §§ 502(q) and (r) of the FDCA and parallel state laws by engaging in false and misleading advertising of Essure®.

201. Defendants continue to sell their product with misleading and false advertising in violation of the conditions of the Essure® CPMA and state laws.

202. The marketing campaign for Essure® was described by Defendants as follows: "Through the use of public relations and targeted advertising, we intend to increase awareness of Essure® among consumers, general practitioners and the broader medical community. In April 2003, we presented Essure® at the annual conference of the American College of Obstetricians and Gynecologists. At this meeting, we had two presentations and there was a Continuing Medical Education, or CME, accredited symposium with Essure® as the main topic. In early June 2003, we commenced a direct mail campaign

to 500,000 women in the Atlanta and Chicago areas, with the goal of encouraging these women to contact our call center for additional information. In turn, our call center has the ability to offer a referral to a practicing Essure® physician in a consumer's area. We had also conducted regional advertisement in a variety of magazines, such as *Parents* and *Self."*

203. Defendants developed this marketing strategy with the help, in part, by St. Louis, Missouri physician and Key Opinion Leader, Dr. David Levine. Dr. Levine's peer-review of articles portraying Essure® positively, promotion of Essure® in publications, training other physicians on the Essure® procedure, commenting on Essure® press releases by Conceptus, and authoring a number of white papers touting the benefits of Essure®. This was all in an effort to gain wide-spread acceptance of Essure® with physicians all over the country, including Plaintiffs' home states.

204. In addition, Defendants operated websites for "physicians and patients" and "established a call center for patients are seeking additional information about Essure® and who wish to be referred to physicians that are trained to perform the Essure® procedure. Physicians that we refer our patients to are those that have chosen to participate in our Essure® Accredited Practice program aimed at providing an optimal patient experience." In reality, the training and medical comprehensiveness of the Essure® Accredited Practice program is a falsehood.

205. Defendants knew or should have known Essure®'s marketing campaign claims included misrepresentations and omissions of material safety information. At the February 19, 2007 fourth quarter earnings call, Conceptus' CEO stated the role of this campaign was to "educate patients on the benefits and drive them to the physician's office asking for Essure®."

206. At the February 19, 2007 fourth quarter earnings call, he further stated, "We are stressing the differences between the Essure® procedure, and the tubal that are of primary concern to each audience the patient and the physician. For patients, the message is no cutting, no going under general anesthesia, no recovery, no hormones, and no guessing…. For physicians, we are capitalizing on their position of trust with the patient and the obvious choice for them to recommend Essure®, a true office procedure with superior effectiveness. These messages carry not only to OB GYNs but also through direct mail to family and general practitioners who often refer out but do not perform tubal ligations. We believe these docs can be strong endorsers of Essure® as well."

207. Defendants willful disseminated false and misleading information at a time when they knew or should have known there were no reasonable grounds for believing these claims to be true when considered in light of the post-market safety information in the possession of Defendants.

208. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose the health hazards and risks associated with Essure® to the FDA, physicians, and patients. Instead, Defendants marketed, advertised, and promoted Essure® while failing to warn or otherwise ensure the safety of its users in violation of parallel state law, including Missouri law, the Essure® CPMA, and FDA regulations.

209. Defendants advertised, promoted, and marketed on their websites, in print and/or video advertisements, brochures, and fact sheets stating the following about Essure®, while failing to report the actual material facts:

a. The Essure® patient brochure stated Essure® was the "[o]nly FDA approved female sterilization procedure to have zero pregnancies in the clinical trials" or words to that effect. However, there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Additionally, several pregnancies were reported subsequent to Essure® implantation. From 1997 to 2005, 64 pregnancies were reported to Defendants. An Adverse Event Report related to the ESS 205 device dated October 3, 2006 evidences an ectopic pregnancy, which can be life-threatening to the mother, after the three-month Confirmation Test was confirmed. Furthermore, a recent study indicates that women implanted with Essure® have a ten times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater.

b. The Essure® website, print advertising, and patient brochure described Essure® as "[s]urgery-free" or words to that effect. However, Essure® is not "surgery-free." All Essure® procedures are done under hysteroscopy, which is a surgical procedure. Defendants also failed to disclose post-market adverse events arising from the implant, and that many of those events required surgery to remove the device. In reality, a recent controlled study of this device found that women who were implanted with the Essure®

device were ten times more likely to need reoperations over women who had tubal ligations.

c. The Essure® website, print advertising and patient brochure described Essure® as "[w]orry free," and a "simple procedure performed in your doctor's office" that takes "less than 10 minutes" and "requires no downtime for recovery" and "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures" or words to that effect. However, Defendants concealed and failed to report complaints of perforations and pain that occurred as a result of Essure® as noted above. Essure® can cause women serious, life-altering complications including, but not limited to, debilitating pain, heavy bleeding necessitating medication, and/or additional surgical procedures, allergic reactions (including, but not limited to, rashes, itching, bloating, swelling, headaches, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications. Defendants failed in their post-market obligations to monitor and report these serious adverse events.

d. The Essure® website, print advertising and patient brochure stated "[t]he Essure® inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place" or words to that effect. However, the micro-inserts do not necessarily remain secure and can migrate and/or be expelled by the body, as evidenced by the multiple complaints concerning perforation that were inadequately monitored and reported by the Defendants.

e. The Essure® website, print advertising and patient brochure stated the "Essure® inserts are made from the same trusted, silicone free material used in heart stents" or words to that effect. However, the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers that trigger inflammation and scar tissue growth. The PET fibers also degrade and leach carcinogens when in temperatures over 65 degrees and the human body is an average of 98 degrees, 33 degrees hotter than when degradation begins. Studies related to PET fiber degradation and leaching became increasingly available post-market, yet the Defendants never warned about it or reconsidered safer alternative materials. Importantly, the PET fibers are not designed or

manufactured for use in human implantation. Moreover, the PET fibers are made of the same materials as the PVT material in some vaginal meshes, which have a high rate of expulsion. The Essure® inserts also contain nickel, which can cause severe reactions in patients. Like the PET fibers, studies became available post-market that put the Defendants on notice of the dangers of nickel to implanted women, yet the Defendants failed to adequately warn about it until it was too late for many women and failed to implement safeguards given this danger.

f. The Essure® website, print advertising, and patient brochure stated "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Essure® is not "surgery-free" and can cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications. Defendants failed in their post-market obligations to monitor and report these serious adverse events.

g. The Essure® website, print advertising, and patient brochure stated "Essure® is the most effective permanent birth control available—even more effective than tying your tubes or a vasectomy" or words to that effect. Yet, Defendants' SEC Form 10-K filing shows that Defendants never did a comparison to a vasectomy or tubal ligation. Defendants admitted, "We did not conduct a clinical trial to compare the Essure® procedure to laparoscopic tubal ligation."

h. The Essure® website claims "[c]orrect placement . . . is performed easily because of the design of the microinsert" or words to that effect. However, Defendants admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in one out of seven clinical participants. Moreover, Defendants failed to warn of the dangers associated with the hysteroscopic procedure, a necessary part of implantation of the device.

i. The Essure® physician training manual states "[t]he PET fibers are what caused the tissue

growth," and Essure® "works with your body to create a natural barrier against pregnancy" or words to that effect. However, during the PMA meeting with the FDA in 2002, Defendants represented that the trauma caused by the expanding coil striking the fallopian tubes is what causes the inflammatory response of the tissue, indicating the dangerous PET fibers are entirely unnecessary.

210. Doctors and patients, including Plaintiffs and their implanting physicians, relied on the misrepresentative marketing strategy developed by Defendants in Missouri.

211. Physicians purchased Essure® kits from Defendants and then performed the procedure on patients after becoming certified and trained by Defendants. During 2008 alone, Conceptus added over 2,000 new physicians to Essure® training and certified over 2,000 physicians to perform Essure®.

212. On April 21, 2009, at the first quarter Conceptus earnings call, Conceptus' CEO stated "We train and provide programs in all of the elements that go into a successful experience for the patient including office staff training, equipment selection, and other procedures, room infrastructure, physician counseling skills, reimbursement, and referral network building."

213. Defendants pioneered a sales plan aimed at physicians that placed profits above patient care. At the 2008 fourth quarter Conceptus earnings call, Defendants emphasized physicians would "bank" more from performing an Essure® procedure in the office, rather than tubal ligation in the hospital. Defendants noted that some physicians had very high rates of utilization and were either referring patients who request tubal ligation to other doctors or "converting" patients to the Essure® procedure.

214. Defendants advertised, promoted, and marketed on their websites, in print and/or video advertisements, brochures, and fact sheets the following statements about physicians performing the Essure® procedure, while failing to report the actual material facts:

a. "An Essure® trained doctor inserts spring-like coils, called micro-inserts" and "[p]hysicians must be signed-off to perform Essure® procedure" or words to that effect. However, Defendants failed to adequately train the implanting physicians and "signed-off" on implanting physicians who did not have the requisite training.

b. The "Essure® training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and

manage technical issues related to the placement of Essure® micro-inserts for permanent birth control" or words to that effect. However, Defendants failed to adequately train the implanting physicians;

c. "In order to be trained in Essure® you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure®" or words to that effect. However, Defendants "signed off" on physicians who were not skilled operative hysteroscopists in order to monopolize and capture the market, including the implanting physicians, and often utilized sales representatives to "train" physicians.

d. "In order to be identified as a qualified Essure® physician, a minimum of one Essure® procedure must be performed every 6-8 weeks" or words to that effect. However, Defendants "signed off" on "Essure® physicians" who did not perform the procedure every 6-8 weeks.

215. Doctors and patients, including Plaintiffs and their implanting physicians, relied on these omissions and/or misrepresentations by Defendants.

216. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendants, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws."

217. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, including Missouri law, but also failed to provide information that was necessary for the medical and scientific community to protect each patient's interest. Because the Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the Essure® device, the public's knowledge of the risks associated with the Essure® device were seriously hampered and delayed. This delay of information endangered patient safety, including Plaintiffs' safety.

218. Only after the FDA forced Defendants to disclose the withheld information did the medical community become aware of this information, including data concerning the frequency, severity, and

permanence of complications associated with the prescription and implementation of the Essure® device.

219. This belated, untimely release of relevant information led to an increasing number of adverse events being reported to the FDA about Essure® from patients and physicians.

220. Until late 2013, women adversely affected by Essure® had no convenient method of reporting their problems directly to the FDA, and thus they reported their problems to Conceptus or Bayer. The FDA learned of an overwhelming number of Essure® adverse events only after women were no longer forced to report their problems directly to Conceptus or Bayer.

221. Between Essure®'s inception in 2002 until 2015, the FDA received approximately 9,900 medical device reports (MDRs) related to safety problems with the device. Of those 9,900 MDRs, 8,950 reports were received between October 26, 2013 and December 31, 2015.

222. Changes in available reporting mechanisms directly caused the explosion of adverse event reports that became public after October of 2013.

223. In response to continued public complaints, on September 24 and 25, 2015, the FDA convened a public hearing concerning the safety and efficacy of the Essure® device. At that public hearing, Defendants continued to misrepresent the safety and efficacy of Essure®:

a. Defendants testified that the efficacy rates for Essure® are 99.6%. In reality, studies show that the chances of becoming pregnant with Essure® are higher than with tubal ligations and higher than the rates reported by Bayer to the FDA at the public hearing.

b. Defendants testified that skin patch testing is not a reliable predictor of clinically significant reactions to nickel-containing implantable devices, including Essure®. Despite this, Bayer told physicians and patients that a nickel sensitivity test was sufficient to determine whether a patient was a suitable candidate for an Essure® device.

c. Defendants testified that Essure® was an alternative to laparoscopic tubal ligation and that Essure® is a safe and effective method of permanent birth control. In reality, studies show that the chances of becoming pregnant with Essure® are higher than with tubal ligations, and Essure® patients are much more likely to require additional surgeries to correct complications associated with the sterilization procedure.

d. Defendants testified that most of the reports of adverse events to the FDA have come from

consumers and not Defendants, which is unusual. In reality, Defendants failed to report thousands of the complaints of adverse events that it had received.

224. Defendants' conduct violated the Essure® CPMA, parallel state laws regarding post-marketing conduct, and the FDA post-marketing regulations, which ultimately prevented Plaintiffs, physicians, and the public from understanding the true nature of Essure®'s adverse events, risks, and ineffectiveness.

FDA REQUIRES BLACK BOX WARNING FOR ESSURE®

225. On February 29, 2016, the FDA announced "actions to provide important information about the risks of using Essure® and to help women and their doctors be better informed of the potential complications associated with" the device. The FDA took the following actions:

a. The FDA is requiring a black box warning on Essure® to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure® also warns: "Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device."

b. The FDA is requiring Defendants to implement a Patient Decision Checklist "to help to ensure women receive and understand information regarding the benefits and risks" of Essure®. The FDA's draft Patient Decision Checklist is a five-page document that the physician will discuss with each patient interested in using the device. The patient must initial after each topic of discussion, and both the physician and patient must sign the document. The topics for discussion include, *inter alia*, the risks for "adverse events including persistent pain, device puncture of the uterus and/or fallopian tubes ('perforation'), or movement of the device into the abdomen or pelvis ('intra-peritoneal migration')"; "allergy or hypersensitivity reactions"; symptoms such as changes in skin (rash, itching), "chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting"; "joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes"; the fact that

"there is no reliable test to predict ahead of time who may develop a reaction to the device"; the possibility that the Essure® device "can move after placement," possibly becoming ineffective at preventing pregnancy or leading to "serious adverse events such as bleeding or bowel damage, which may require surgery to address"; and the fact that if the Essure® device has to be removed after placement, it will require surgery to remove and possibly a hysterectomy.

c. The FDA has also ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real world environment." The study must provide data on "the risks associated with Essure® and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure® device. The study will also evaluate how much these complications affect a patient's quality of life. . . . The FDA will use the results of this study to determine what, if any, further actions related to Essure® are needed to protect public health."

226. Unfortunately, this new warning, labeling, and patient decision checklist came too late to warn Plaintiffs of the true risks of Essure®. Had the Defendants complied with their federal regulatory duties and their duties under Missouri law by warning about and reporting the known risks and complications in a timely fashion, the Plaintiffs and their physicians would have had this relevant, critical information available to them before the implantation of the Essure® device.

227. In addition, Congress is calling for the removal of Essure® from the market. Pennsylvania Congressman Mike Fitzpatrick introduced a bipartisan bill entitled the "E-Free Act" on November 4, 2015 to ban sales of the Essure® device.

228. Congressman Fitzpatrick demanded that Bayer immediately end production of a product that poses such a danger to patient safety.

229. If an unintended pregnancy occurs due to a failure of the Essure® inserts, the inserts present a risk of fetal death, either through ectopic pregnancy or through premature rupture of membranes ("PROM"). PROM may lead to respiratory distress syndrome, infections/sepsis, placental abruption, and fetal death.

230. A consulting firm specializing in medical device post-marketing surveillance, Device Events, recently analyzed data provided to the FDA for the Congressman. The analysis uncovered raw data showing a total of 303 fetal deaths among women who had the Essure® device and revealed discrepancies in Defendants' reporting practices. Previously, the agency had believed that there were only five such cases.

231. The analysis showed that the manufacturers' reports were falsely marked as mere injury or malfunction reports. However, they described instances of miscarriage, abortion or fetal death, and should have been categorized as "death" reports.

232. This bill has been renamed "Ariel Grace's Law," and it would permit lawsuits against manufacturers of Class III devices. It calls for the preemption label to be removed from Essure® as well.

233. Congressman Fitzpatrick subsequently wrote directly to the Center for Devices and Radiological Health at the FDA and urged them to immediately consider the data due to its grave nature.

234. At all relevant times, Defendants' Essure® product was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

PLAINTIFF-SPECIFIC ALLEGATIONS

235. Plaintiff Sitafia Langston was implanted with Essure® on August 3, 2006 in Saint Louis, MO. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, blurred vision, and depression. She had surgery to remove the Essure® implant on April 8, 2016. The injuries that Plaintiffs suffered as a result of these coils are a direct and proximate result of the Bayer Defendants' failure to disseminate accurate information regarding the safety profile of their product. Without that information, Plaintiffs were unable to make an informed decision regarding safer alternatives.

236. Plaintiff Tammy Pappelis was implanted with Essure® on February 22, 2011 in Hastings, MN. As a result of her implantation with Essure® she suffered injuries, including: migration of implant and perforation of organs. She had surgery to remove the Essure® implant on December 28, 2011.

237. Plaintiff Danielle Carpenter was implanted with Essure® on October 1, 2014. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy. She had surgery to remove the Essure® implant on December 1, 2015.

238. Plaintiff Misty Roxanne Isennock was implanted with Essure® on January 31, 2013 in Chattanooga, TN. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, pain, pelvic and back pain, root canals, brain fog, depression/anxiety, forgetfulness, hair loss, unexplained bruising, large ovarian cysts, fevers, hives, and emotional distress. She had surgery to remove the Essure® implant on September 28, 2016.

239. Plaintiff Alexandra Bunner was implanted with Essure® on January 0, 1900. As a result of her implantation with Essure® she suffered injuries. She had surgery to remove the Essure® implant on May 1, 2015.

240. Plaintiff Madel Hernandez was implanted with Essure® on January 1, 2008 in Mansfield, TX. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, migration of implant, pain, skin rash, bloating, abdominal and back pain, and leg cramps. She had surgery to remove the Essure® implant on September 1, 2016.

241. Plaintiff Tiffany D. Cook was implanted with Essure® on July 1, 2013 in Beckley, WV. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy. She had surgery to remove the Essure® implant on September 1, 2016.

242. Plaintiff Megan Oleszczuk was implanted with Essure® on January 12, 2011 in Ephrata, PA. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pelvic and back pain, bloating, and heavy menstrual cycles. She had surgery to remove the Essure® implant on August 18, 2016.

243. Plaintiff Erika R. Rodriguez was implanted with Essure® on December 7, 2011 in Albuquerque, NM. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, weight gain, hair loss, anxiety, abdominal pain, fatty & enlarged liver, and migraines. She had surgery to remove the Essure® implant on May 21, 2014.

244. Plaintiff Amy L. Hill was implanted with Essure® on March 21, 2007 in Jonesboro, AR. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, adenomyosis, broken teeth, auto immune disorder, weight gain, hair loss, depression, and joint pain. She had surgery to remove the Essure® implant on May 9, 2014.

245. Plaintiff LaQueesha M. Jennings was implanted with Essure® on August 6, 2009 in Wichita,

KS. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, pain, abdominal pain, painful intercourse, hot flashes, hair loss, UTIs, loss of sleep, breast pain & tenderness, and headaches. She had surgery to remove the Essure® implant on August 2, 2016.

246. Plaintiff Isla Lyssette Ramirez was implanted with Essure® on October 12, 2011. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, skin rash, pelvic pain, memory loss, painful intercourse, coil migration, vertigo, and hair loss. She had surgery to remove the Essure® implant on August 19, 2015.

247. Plaintiff Cynthia Carol Mains was implanted with Essure® on January 1, 2008 in Fort Thomas, KY. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, abdominal swelling, weight gain, anxiety, fatigue, uterine fibroids, tumors, cysts on fallopian tubes, and joint pain. She had surgery to remove the Essure® implant on May 24, 2016.

248. Plaintiff Jessica Mowafy-Francis was implanted with Essure® on June 1, 2011 in Chandler, AZ. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, miscarriage, autoimmune disorder, long cycles, and stomach pains. She had surgery to remove the Essure® implant on December 3, 2015.

249. Plaintiff TraVivra Arbabe was implanted with Essure® on September 1, 2011 in Kalamazoo, MI. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, and pain. She had surgery to remove the Essure® implant on February 1, 2015.

250. Plaintiff Cynthia N. Lorenza was implanted with Essure® on August 1, 2011 in West Branch, MI. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, nausea, weakness, bloating, hair loss, mood swings, and memory problems. She had surgery to remove the Essure® implant on December 10, 2014.

251. Plaintiff Kandice P. Hill was implanted with Essure® on September 25, 2013 in Austin, TX. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, pain, bloating, anxiety, and deteriorating teeth. She had surgery to remove the Essure® implant on July 22, 2016.

252. Plaintiff Melissa Bergs was implanted with Essure® on September 10, 2010 in Kalamazoo,

MI. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, pain, dizziness, painful menstruation, brain fog, and bloating. She had surgery to remove the Essure® implant on January 26, 2015.

253. Plaintiff Alecia M. Nauman was implanted with Essure® on October 8, 2015 in Bethlehem, PA. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, migration of implant, and pain. She had surgery to remove the Essure® implant on June 28, 2016.

254. Plaintiff Nicole DeMauro was implanted with Essure® on August 1, 2013 in Worcester, MA. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, migration of implant, and pain. She had surgery to remove the Essure® implant on April 1, 2014.

255. Plaintiff WaKeshia Hughes was implanted with Essure® on January 1, 2010 in Detroit, MI. As a result of her implantation with Essure® she suffered injuries. She had surgery to remove the Essure® implant on January 1, 2015.

256. Plaintiff Janet M. Chessor was implanted with Essure® on March 23, 2010 in Tupelo, MS. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, pain, cramping, clotting, migraines, weight gain, and body aches. She had surgery to remove the Essure® implant on June 9, 2016.

257. Plaintiff Dawn Renee Smith was implanted with Essure® on December 29, 2011 in Oxford, OH. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, pain, lower back and hip pain, heartburn, migraines, abdominal pain, joint pain, and teeth chipping. She had surgery to remove the Essure® implant on June 7, 2016.

258. Plaintiff Shontavia K. Williams was implanted with Essure® on March 1, 2014 in Dallas, TX. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, hair loss, depression, and headaches. She had surgery to remove the Essure® implant on May 27, 2015.

259. Plaintiff Hope L. Lopez was implanted with Essure® on July 2, 2015 in Glendale, AZ. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, perforation of organs, pain, and irregular & heavy periods. She had surgery to

remove the Essure® implant on February 3, 2016.

260. Plaintiff Marando E. Acy was implanted with Essure® on January 1, 2006 in Clovis, NM. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, cramping, blood clots, numbness, tingling, vision blurry, headaches, and forgetfulness. She had surgery to remove the Essure® implant on June 1, 2016.

261. Plaintiff Racheal Lynn Bollmeyer was implanted with Essure® on March 1, 2011 in Murfreesboro, TN. As a result of her implantation with Essure® she suffered injuries. She had surgery to remove the Essure® implant on June 2, 2016.

262. Plaintiff Jenene J. Hatchard was implanted with Essure® on February 1, 2011 in Montclair, NJ. As a result of her implantation with Essure® she suffered injuries. She had surgery to remove the Essure® implant on June 15, 2015.

263. Plaintiff Tina M. Bacorn was implanted with Essure® on April 2, 2010 in Bettendorf, IA. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, migration of implant, perforation of organs, pain, anemia, ovarian cysts, fatigue, painful intercourse, and weight gain. She had surgery to remove the Essure® implant on March 1, 2016.

264. Plaintiff Diana Via was implanted with Essure® on December 1, 2010 in Fredericksburg, VA. As a result of her implantation with Essure® she suffered injuries, including: pain, pelvic pain, weight gain, allergies, migraines, and chronic fatigue. She had surgery to remove the Essure® implant on June 15, 2016.

265. Plaintiff Jennifer Rodrigues was implanted with Essure® on June 27, 2012 in Massillon, OH. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, headaches, fatigue, discharge, and painful intercourse. She had surgery to remove the Essure® implant on April 12, 2016.

266. Plaintiff Patricia Mendez was implanted with Essure® on February 1, 2007 in Edinburg, TX. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, pain, bloating, anemia, headaches, and weight gain. She had surgery to remove the Essure® implant on April 14, 2016.

267. Plaintiff Perla P. Jimenez was implanted with Essure® on December 10, 2008 in Austin, TX.

As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, migration of implant, perforation of organs, pain, and memory loss. She had surgery to remove the Essure® implant on April 15, 2016.

268. Plaintiff LeeAnn Ferrell was implanted with Essure® on December 1, 2012 in Mount Vernon, IL. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, fatigue, brain fog, irregular periods, nickel allergy, seizures, hair loss, bloating, and night sweats. She had surgery to remove the Essure® implant on June 9, 2016.

269. Plaintiff TynekMinay Lenora Williams was implanted with Essure® on October 1, 2013 in Charlotte, NC. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, hair loss, painful intercourse, gallbladder removal, lack of sex drive, migraines, back pain, and lack of energy. She had surgery to remove the Essure® implant on April 6, 2016.

270. Plaintiff Shanna Higgs-Latham was implanted with Essure® on May 23, 2011 in Denton, TX. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, bloating, headaches, weight gain, high blood pressure, and anxiety. She had surgery to remove the Essure® implant on June 13, 2016.

271. Plaintiff Brandy Minder was implanted with Essure® on May 1, 2011 in Mount Vernon, IL. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, perforation of organs, and pain. She had surgery to remove the Essure® implant on June 26, 2016.

272. Plaintiff Cathy Leigh Rademacher was implanted with Essure® on March 17, 2015 in McAllen, TX. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, migration of implant, left hip injury from coil migrating, severe swelling, severe joint pain, and compromised immune system. She had surgery to remove the Essure® implant on March 16, 2016.

273. Plaintiff Marisa A. Vieira was implanted with Essure® on October 9, 2013 in Providence, RI. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, depression, weight gain, painful sex, headaches, and bloating. She had surgery to remove the Essure® implant on July 7, 2015.

274. Plaintiff Melissa Bloomfield was implanted with Essure® on April 1, 2015 in Marion, OH. As a result of her implantation with Essure® she suffered injuries, including: migration of implant and perforation of organs. She had surgery to remove the Essure® implant on July 27, 2016.

275. Plaintiff Mary Garza was implanted with Essure® on August 1, 2011 in San Antonio, TX. As a result of her implantation with Essure® she suffered injuries, including: ectopic pregnancy, fracturing of the implant, hysterectomy, migration of implant, perforation of organs, pain, miscarriage, fatigue, weight gain, and headaches. She had surgery to remove the Essure® implant on July 28, 2016.

276. Plaintiff Christine Bond was implanted with Essure® on September 23, 2013 in Salt Lake City, UT. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, perforation of organs, and pain. She had surgery to remove the Essure® implant on July 29, 2016.

277. Plaintiff Elizabeth Goodwin was implanted with Essure® on June 4, 2010 in Kankakee, IL. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, hysterectomy, migration of implant, and pain, bloating. She had surgery to remove the Essure® implant on April 8, 2016.

278. Plaintiff Angela C. Brink was implanted with Essure® on May 27, 2010 in Dansville, NY. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, hysterectomy, pain, migraines, painful intercourse, depression, and mood swings. She had surgery to remove the Essure® implant on April 27, 2015.

279. Plaintiff Nicola M. Byrd-Holliday was implanted with Essure® on September 1, 2013 in Greenville, SC. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, perforation of organs, and pain. She had surgery to remove the Essure® implant on August 6, 2015.

280. Plaintiff Samantha Cain was implanted with Essure® on July 17, 2015 in Desoto, TX. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, migration of implant, pain, hair loss, rotting teeth, depression, anxiety, inflammation, weight gain, no energy, loss sex drive, and abdominal pain. She had surgery to remove the Essure® implant on May 31, 2016.

281. Plaintiff Nieves Hernandez was implanted with Essure® on June 12, 2013 in Chicago, IL. As

a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, pain, skin rash, fatigue, headaches, nickel allergy, and mood swings. She had surgery to remove the Essure® implant on January 7, 2016.

282. Plaintiff Catherine L. Terry was implanted with Essure® on September 1, 2014 in Plano, TX. As a result of her implantation with Essure® she suffered injuries, including: perforation of organs, and pain. She had surgery to remove the Essure® implant on August 19, 2016.

283. Plaintiff Tiffani Bell was implanted with Essure® on November 9, 2006 in Manchester, NH. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, pain, skin rash, miscarriage, migraines, and numbness. She had surgery to remove the Essure® implant on July 17, 2015.

284. Plaintiff Jennifer Rupp was implanted with Essure® on May 10, 2013 in Tacoma, WA. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, migration of implant, perforation of organs, pain, skin rash, fatigue, migraines, bloating, and brain fog. She had surgery to remove the Essure® implant on September 18, 2015.

285. Plaintiff Shauna D. Yazzie was implanted with Essure® on March 4, 2011 in Flagstaff, AZ. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, skin rash, hair loss, weight gain, no energy, bloating, body aches, fatigue, and itching. She had surgery to remove the Essure® implant on September 29, 2016.

286. Plaintiff Candy Lynn Claudio was implanted with Essure® on September 1, 2009 in Muskegon, MI. As a result of her implantation with Essure® she suffered injuries. She had surgery to remove the Essure® implant on April 23, 2015.

287. Plaintiff Julley L Meyer was implanted with Essure® on August 2, 2012 in Russellville, AR. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, pain, fatigue, headaches, vomiting, and hair loss. She had surgery to remove the Essure® implant on June 30, 2014.

288. Plaintiff Tyhisha Hudson was implanted with Essure® on July 22, 2011 in Philadelphia, PA. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, headaches, nausea, depression, and back pain. She had surgery to remove the Essure® implant on July 24, 2015.

289. Plaintiff Renee Lynn Atkins was implanted with Essure® on November 26, 2008 in Belleville, IL. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant and hysterectomy. She had surgery to remove the Essure® implant on August 1, 2015.

290. Plaintiff Nichole Short was implanted with Essure® on January 0, 1900 in Raleigh, NC. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, perforation of organs, pain, and long cycles. She had surgery to remove the Essure® implant on September 29, 2015.

291. Plaintiff Beth A. Park was implanted with Essure® on December 1, 2008. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, migration of implant, pain, bone pain, dry eyes, allergies, skin problems, vision trouble, and photosensitivity. She had surgery to remove the Essure® implant on October 21, 2015.

292. Plaintiff Jennifer C. Bennion was implanted with Essure® on July 1, 2013 in Vernal, UT. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, migration of implant, perforation of organs, pain, skin rash, allergy nickel, hair loss, pelvic pain, constant bloating, lack of energy, breast tenderness, anxiety, and tooth pain. She had surgery to remove the Essure® implant on October 3, 2016.

293. Plaintiff Tabitha Harris-Graham was implanted with Essure® on August 6, 2013 in Bullhead City, AZ. As a result of her implantation with Essure® she suffered injuries, including: migration of implant, perforation of organs, and hair loss. She had surgery to remove the Essure® implant on October 19, 2016.

294. Plaintiff Lisa M. Wallace was implanted with Essure® on June 23, 2011 in Madison, WI. As a result of her implantation with Essure® she suffered injuries, including: pain, cysts, scar from removal, pelvic pain, painful intercourse, and irregular bleeding. She had surgery to remove the Essure® implant on September 9, 2015.

295. Plaintiff Kimberly S. Holland was implanted with Essure® on May 30, 2012 in Columbus, OH. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, and pain. She had surgery to remove the Essure® implant on November 12, 2016.

296. Plaintiff Nicole Amber McAleese was implanted with Essure® on January 1, 2012 in

Charlotte, NC. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, migration of implant, and pain. She had surgery to remove the Essure® implant on August 19, 2015.

297. Plaintiff Emilie R. Smith was implanted with Essure® on November 28, 2006 in Jacksonville, NC. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, perforation of organs, pain, incontinence, and low sex drive. She had surgery to remove the Essure® implant on December 2, 2015.

298. Plaintiff Dawn Seaney was implanted with Essure® on May 4, 2010 in Paragould, AR. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, back pain, clotting, hair Loss, and neuropathy. She had surgery to remove the Essure® implant on October 22, 2014.

299. Plaintiff Mariola Genge was implanted with Essure® on May 1, 2008 in Orland Park, IL. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, and pain. She had surgery to remove the Essure® implant on June 5, 2015.

300. Plaintiff Crystal Trautman was implanted with Essure® on May 27, 2014 in Saint Louis, MO. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, migration of implant, pain, abdominal pain, and heavy menstrual cycles. She had surgery to remove the Essure® implant on May 4, 2015.

301. Plaintiff Anna M Dukes was implanted with Essure® on September 24, 2008 in Fremont, MI. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, pelvic pain, cramping sensations, and hair loss. She had surgery to remove the Essure® implant on December 18, 2015.

302. Plaintiff La'Toya Jones was implanted with Essure® on August 21, 2013 in Smithfield, NC. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, pain, sick, cramps, weight gain, pain, and bleeding. She had surgery to remove the Essure® implant on March 9, 2015.

303. Plaintiff Shelly Marie Scott was implanted with Essure® on January 1, 2008 in Indianapolis, IN. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding,

hysterectomy, pain, bloating, cramping, and polycystic ovarian syndrome. She had surgery to remove the Essure® implant on February 1, 2015.

304. Plaintiff Raquel B. Flores was implanted with Essure® on February 1, 2009 in CA. As a result of her implantation with Essure® she suffered injuries, including: pain, inflammation, anxiety, brain fog, bladder issues, and asthma. She had surgery to remove the Essure® implant on January 27, 2015.

305. Plaintiff Ann Marie Smith was implanted with Essure® on July 16, 2009 in Mobile, AL. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, skin rash, yeast infections, fatigue, metallic taste in mouth, loss of libido, painful intercourse, bleeding after intercourse, migraines, brain fog, bowel issues, enlarged uterus, ovarian cysts, and polyps. She had surgery to remove the Essure® implant on August 5, 2016.

306. Plaintiff Christena Smith was implanted with Essure® on January 1, 2008 in Detroit, MI. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, pain, cyst, and cramping. She had surgery to remove the Essure® implant on August 15, 2014.

307. Plaintiff Misty Jo Gibson was implanted with Essure® on May 25, 2010 in Richland, WA. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, pain, back pain, and headaches. She had surgery to remove the Essure® implant on November 18, 2014.

308. Plaintiff Olivia M. Robinson was implanted with Essure® on July 31, 2008 in Falls Church, VA. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, pain, hair loss, weight gain, headaches, infection, and cramps. She had surgery to remove the Essure® implant on October 1, 2015.

309. Plaintiff Michelle Chavez was implanted with Essure® on July 25, 2013 in Albuquerque, NM. As a result of her implantation with Essure® she suffered injuries, including: pain, pain during intercourse, depression, itching, and weight gain. She had surgery to remove the Essure® implant on April 30, 2014.

310. Plaintiff Helen Pauline Huxford was implanted with Essure® on May 18, 2007 in Newport News, VA. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, pain, painful intercourse, migraines, bloating, fibroids, and cysts. She had surgery to remove the Essure® implant on July 26, 2016.

311. Plaintiff Lisa Marie Bundy was implanted with Essure® on November 1, 2012. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, lower abdomen pain, and brain fog. She had surgery to remove the Essure® implant on April 21, 2015.

312. Plaintiff Katherine Barnett was implanted with Essure® on October 19, 2008 in Osage Beach, MO. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, cysts, inflammation, leg swelling, weight gain, hair loss, hair damage, and high blood pressure. She had surgery to remove the Essure® implant on March 9, 2016.

313. Plaintiff Harley Hernandez was implanted with Essure® on October 20, 2009 in Springfield, MO. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, migration of implant, pain, longer menstruation, and headaches. She had surgery to remove the Essure® implant on May 19, 2016.

314. Plaintiff Tracey D. Koontz was implanted with Essure® on November 20, 2012 in Kansas City, MO. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, and miscarriage. She had surgery to remove the Essure® implant on May 20, 2016.

315. Plaintiff Tracey Peterson was implanted with Essure® on November 17, 2011 in Saint Louis, MO. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, bleeding post intercourse, psoriasis, brain fog, painful menstrual cycles, and pain during intercourse. She had surgery to remove the Essure® implant on June 2, 2016.

316. Plaintiff Victoria D. Lawson was implanted with Essure® on January 1, 2011 in Ballwin, MO. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, headaches, painful intercourse, lack of sex drive, mood swings, hair loss, hives, and constipation,. She had surgery to remove the Essure® implant on July 12, 2016.

317. Plaintiff Breeanna D. Jackson was implanted with Essure® on July 1, 2007 in Saint Louis, MO. As a result of her implantation with Essure® she suffered injuries, including: migration of implant,

perforation of organs, sick, and weight gain. She had surgery to remove the Essure® implant on August 23, 2016.

318. Plaintiff Sheba M. Whitiker was implanted with Essure® on April 25, 2008 in Monticello, AR. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, hysterectomy, perforation of organs, pain, nausea, headaches, and high blood pressure. She had surgery to remove the Essure® implant on January 14, 2015.

319. Plaintiff Marcy Senica was implanted with Essure® on June 1, 2009 in Peru, IL. As a result of her implantation with Essure® she suffered injuries, including: ectopic pregnancy, heavy bleeding, migration of implant, pain, miscarriage, painful sex/joints , bloating, headaches, and fatigue. She had surgery to remove the Essure® implant on January 29, 2016.

320. Plaintiff Terry Williams was implanted with Essure® on January 1, 2007 in Puyallup, WA. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, and perforation of organs. She had surgery to remove the Essure® implant on March 19, 2015.

321. Plaintiff Cecilia Salas was implanted with Essure® on July 11, 2014 in Austin, TX. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, migration of implant, pain, skin rash, metal taste, nausea, and abdominal pain. She had surgery to remove the Essure® implant on April 13, 2016.

322. Plaintiff Kristina Pitts was implanted with Essure® on September 10, 2008 in San Antonio, TX. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, migration of implant, pain, miscarriage, depression, numbing of hands, unbalanced hormones, bloating, headaches, night sweats, and polyps. She had surgery to remove the Essure® implant on April 22, 2016.

323. Plaintiff Jhonancy Francois was implanted with Essure® on May 20, 2015 in Pasadena, TX. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, migration of implant, and pain. She had surgery to remove the Essure® implant on August 16, 2016.

324. Plaintiff Stacie Calixte was implanted with Essure® on July 22, 2015 in Chestnut Hill, MA. As a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, pain, and allergic reaction. She had surgery to remove the Essure® implant on September 29, 2015.

325. Plaintiff Tahina Smith was implanted with Essure® on October 31, 2013 in Defiance, OH. As

a result of her implantation with Essure® she suffered injuries, including: fracturing of the implant, heavy bleeding, hysterectomy, migration of implant, perforation of organs, pain, pelvic pain, cramps, excessive bleeding, nausea, headaches, and bloating. She had surgery to remove the Essure® implant on October 17, 2016.

326. Plaintiff Danielle Congleton was implanted with Essure® on January 1, 2012 in Littleton, CO. As a result of her implantation with Essure® she suffered injuries, including: hysterectomy, migration of implant, bleeding between periods and intercourse, pelvic and lower back pain, and excessive bleeding. She had surgery to remove the Essure® implant on October 18, 2016.

327. Plaintiff Takesha Dublin was implanted with Essure® on July 1, 2010 in Rome, GA. As a result of her implantation with Essure® she suffered injuries, including: heavy bleeding, migration of implant, pain, and tubal removal. She had surgery to remove the Essure® implant on November 14, 2016.

328. Plaintiffs exercised reasonable diligence in investigating potential causes of their symptoms by discussing her injuries with healthcare providers. None of Plaintiffs' conversations with their healthcare providers or their research gave Plaintiff a reason to suspect, or reasonably should have given Plaintiffs a reason to suspect, that the Essure® implanted in Plaintiffs were defective.

329. Plaintiffs did not have knowledge or sufficient notice that the level of risk of injuries from Essure® was higher than they were originally lead to believe, nor did they learn of any potential wrongdoing on the part of the manufacturer, until the FDA convened public Essure® hearings in late 2015. Under the facts of this case, Plaintiffs' suits were filed well within the applicable statutory limitations period.

330. Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiffs and their physicians of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct. Plaintiffs diligently filed suit once they discovered the actual facts. Defendants' misconduct and fraudulent concealment of the relevant facts, as described *infra*, tolls any relevant statute of limitations.

331. Defendants are and were under a continuing duty to monitor and disclose the true character,

quality, and nature of Essure®. Because of Defendants' misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendants are estopped from relying on any statute of limitations defense.

CAUSES OF ACTION
FIRST CAUSE OF ACTION - NEGLIGENCE

332. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

333. Defendants formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Essure®, including the Essure® devices that were implanted into Plaintiffs. The testing, development, marketing, promotion, and labeling conducted, in part, in Missouri was integral to Conceptus's ability to distribute Essure® to all Plaintiffs and Plaintiffs' implanting physicians.

334. Defendants had a duty under parallel state law, including Missouri law, to exercise reasonable care to provide adequate warning about the risks and dangers of Essure® that were known or knowable to Defendants at the time of distribution.

335. Defendants breached their duty in that they failed to warn Plaintiffs and their physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Essure® prior to the time of Plaintiffs' implantation, including the actual level of risk and failure to communicate adverse events similar to the injuries suffered by Plaintiffs.

336. Specifically, Defendants breached these duties and violated federal and state law by, *inter alia*: receiving and failing to warn of or report many of the approximately 16,000 complaints about Essure® to the FDA or the public; failing to warn of or report Essure®'s failure to meet its performance specifications or perform as intended under the CPMA and FDA requirements; and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Essure®, including but not limited to:

a. instances of perforation and/or penetration of the fallopian tubes;

b. instances of perforation and/or penetration of the uterus;

c. instances of perforation and/or penetration of the bowel;

d. instances of perforation and/or penetration of the abdominal cavity;

e. instances of perforation and/or penetration of the peritoneal cavity;

f. instances of migration;

g. instances of chronic/persistent abdominal and pelvic pain/cramping;

h. instances of chronic/persistent irregular vaginal bleeding;

i. instances of the device internally separating or breaking into pieces; and

j. instances of adverse events/reactions requiring device removal.

337. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Essure®. Instead, Defendants marketed, advertised, and promoted Essure® while failing to warn or otherwise ensure the safety of its users in violation of state law, including Missouri law, the Essure® CPMA and FDA regulations.

338. In addition, the Essure® CPMA set forth specific reporting requirements—as described above—that obligated Defendants to report:

a. knowledge or information of any adverse reactions, side effects, injuries, toxicity, or sensitivity reactions;

b. unanticipated adverse effects or increases in the frequency of anticipated adverse effects;

c. any knowledge or information of Essure®'s failure to meet device specifications established in the approved CPMA;

d. any changes to the performance of the device;

e. changes to the facility or establishment to manufacture, process, or package the device;

f. whenever there is use of a different facility or establishment to manufacture, process, or package the device;

g. any information from any source that reasonably suggests a device may have caused or contributed to serious injury; and

h. any information from any source that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

339. Defendants negligently failed to comply with the above requirements and failed to take necessary actions—such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs—to advise users of Essure® of the defects and risks described above.

340. Defendants had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded.

341. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs and/or Plaintiffs' physician, regarding the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

342. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, the FDA held a public hearing discussing the risks and benefits of the device and then required a black box warning and Patient Decision Checklist for Essure® that warns of many of the same injuries that Plaintiffs have experienced due to Essure®.

343. Defendants' delay in timely reporting their known complications prevented the Plaintiffs and their physicians from having timely information concerning the real life risks associated with the Essure® device. Had the Plaintiffs received timely and adequate information of these serious risks and adverse events, they would not have agreed to the Essure® implant.

344. Defendants could have included this information in its labeling, physician use materials, and patient pamphlets, which Plaintiffs and their physician reviewed and relied upon, but Defendants chose not to include it. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, physicians began to study Essure® adverse events further and published articles in well-respected medical journals. This information would have been available for review by Plaintiffs and Plaintiffs' physicians.

345. Indeed, if Plaintiffs and Plaintiffs' physicians had been adequately warned of these serious

risks and adverse events, they would not have agreed to or used the Essure® implant. As a proximate and legal result of Defendants' failure to comply with its CPMA and FDA post-marketing regulations, Defendants breached their duty of care to Plaintiffs under parallel state law and caused Plaintiffs past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

346. Defendants owed a duty in all of its several undertakings, including the communication of information concerning Essure®, and to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

347. Defendants, in the course of its business and profession, knowingly and negligently disseminated inaccurate and misleading information through the Essure® marketing strategy developed using Missouri physicians, to physicians concerning the properties and effects of Essure®, with the intent and expectation that physicians would rely on that information in their decisions in recommending and prescribing Essure® for their patients.

348. When Defendants disseminated information through the Essure® marketing strategy developed using Missouri physicians, to physicians and/or patients concerning the properties and effects of Essure®, they knew or should have known that physicians and/or patients would reasonably rely on that information in their decisions concerning the use of Essure®.

349. Defendants disseminated false information, through the Essure® marketing strategy developed using Missouri physicians, as described in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics," to physicians, the medical community, and the public with knowledge that the information was, in fact, false and misleading.

350. Defendants made misrepresentations which are specifically outlined in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics."

351. Defendants made these misrepresentations and concealed adverse information at a time when Defendants knew, or should have known, that Essure® had defects, dangers, and characteristics that were other than what Defendants had represented to consumers and the healthcare industry generally.

352. Defendants had no reasonable grounds for believing these representations were true when they

were made; in fact, Defendants knew the representations to be false.

353. Defendants' breach of their duties under state law parallel their violations of federal law; the Essure® CPMA specifically mandates, and state law independently requires, that any representations regarding the device must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

354. Defendants disseminated the false information, through the Essure® marketing strategy developed using Missouri physicians as referenced above, to physicians, the medical community, and the public with the intention to deceive physicians and their patients and to induce physicians to prescribe Essure® and patients to permit this device to be implanted in their bodies.

355. In willfully supplying the false and misleading information, Defendants negligently failed to exercise reasonable care to ensure that the information disseminated to physicians and patients concerning the properties and effects of Essure® was accurate and not misleading.

356. By failing to ensure representations regarding Essure® were truthful, accurate, and not misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

357. Defendants expected or should have expected that patients, in reliance on false information, who were implanted with Essure® would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to Essure®.

358. Plaintiffs and/or Plaintiffs' physicians did in fact reasonably rely on Defendants' negligent misrepresentations, as Defendants intended.

359. Specifically, Plaintiffs' physicians would have never recommended, and Plaintiffs would have never had Essure® implanted, had they been aware that there had been 16,047 complaints regarding Essure®, or the falsity of the representations specifically delineated in the preceding paragraphs.

360. As a proximate and foreseeable result of the foregoing misrepresentations by Defendants, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

361. Under federal law and regulations, Defendants were under a continuing duty to comply with the requirements listed in their CPMA and with the FDCA in the manufacture, development, promotion,

marketing, labeling, distribution, and sale of Essure®. *See* Essure® CPMA; 21 U.S.C. ch. 9 §§ 301, et seq.

362. Violations of the following federal regulations also constitute violations of Defendants' parallel state law duties and give rise to negligence *per se*: 21 C.F.R. § 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21, C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21 C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.5; 21 C.F.R. § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; 21 C.F.R. § 820.30; 21 § C.F.R. 820.70 and 21 C.F.R. § 820.160.

363. Defendants' conduct also violates their duties under the Sherman Food, Drug, and Cosmetic laws and gives rise to negligence per se: West's Ann. Cal. Health & Safety Code §§ 111295; 111300; 111305; 111440; 111445; and 111450.

364. Plaintiffs are within the class of persons the statutes and regulations protect, and Plaintiffs' injuries are of the type of harm these statutes and regulations are designed to prevent.

365. Defendants' violations of these statutes and regulations proximately caused Plaintiffs' injuries alleged herein.

366. The conditions of the Essure® CPMA incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the CPMA. *See* 21 C.F.R. § 814.82(c).

367. Defendants had a parallel duty under state law, including Missouri law, to exercise reasonable care in testing and inspecting their product, in performing continuing risk-analysis and risk assessments of Essure®, and in marketing Essure® to the public. Defendants also undertook a duty to certify and train physicians on the proper implantation of the device.

368. Defendants were negligent under state law, including Missouri law, in their development, promotion, marketing, distribution, and/or sale of Essure® in one or more of the following particulars:

a. failing to conduct regular risk analysis of its Essure® device, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes;

b. in failing to properly meet the applicable standard of care by not complying with applicable federal regulations;

c. carelessly and negligently selling and distributing Essure® in violation of the CPMA and federal law;

d. negligently incorporating components into Essure® that could not stand up to normal usage;

e. failing to exercise reasonable care in its inspecting and testing of the product;

f. failing to exercise reasonable care to appropriately certify and train physicians on prescribing and implantation of the device.

369. Despite the fact that Defendants knew or should have known that Essure® caused unreasonable, dangerous side effects, Defendants continued to promote and market Essure® to consumers, including Plaintiffs and their healthcare providers.

370. Defendants were cited by the FDA for, *inter alia*:

a. erroneously using non-conforming material in the manufacturing of Essure®;

b. failing to use pre-sterile and post-sterile cages;

c. manufacturing Essure® at an unlicensed facility;

d. manufacturing Essure® for three years without a license to do so;

e. failing to analyze or identify existing potential causes of non-conforming product and other quality problems;

f. failing to track non-conforming product;

g. failing to follow procedures used to control products which did not conform to specifications;

h. failing to have a complete Design Failure Analysis; and

i. failing to document CAPA activities for a supplier correction action.

371. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Essure®.

372. Defendants failed to adequately inspect, test, and validate the materials and components used in the manufacture and assembly of Essure®.

373. Defendants failed to adequately inspect, test, and validate Essure® after completion of assembly and immediately before delivery to Plaintiffs.

374. Because Defendants failed to follow specifications, regulations, and required Good Manufacturing Practices, Plaintiffs' Essure® coils became unpassivated, making it vulnerable to degradation, deterioration, migration, leaching, breakage, and fragmentation.

375. Upon information and belief, when Essure® was manufactured, Defendants had the technological capability to manufacture Essure® in a reasonably safe manner and is held to the level of knowledge of an expert in the field.

376. Plaintiffs were implanted with their Essure® devices between 2002 and 2015. At that time, unbeknownst to the Plaintiffs and their physicians, Defendants had been cited in 2002, 2003, 2008, 2011 and 2014 by the FDA and CDHP for: failure to report complications it knew were associated with Essure®; failure to perform an appropriate Risk Analysis Design Failure Mode Effects Analysis and to undertake Corrective and Preventative Action to address manufacturing defects; use of uncertified materials and non-conformity of the contract manufacturer for not following their own SOP for control of non-conforming material; and failing to maintain proper procedure in inventory transfer. These manufacturing violations affecting the manufacturing quality of Essure® and were not isolated events, but represented ongoing, systematic, and widespread conduct by Defendants that signified problems with the manufacturing process starting before Plaintiffs received their Essure® implants and continuing through at least August 2015.

377. As a proximate and legal result of Defendants' failure to exercise reasonable care and the resulting defective condition of Essure®, the Essure® coils implanted into Plaintiffs caused Plaintiffs' injuries described *infra*. Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

378. WHEREFORE, Plaintiffs pray for judgment against Bayer Defendants, jointly and severally, in an amount in excess of Twenty Five Thousand Dollars ($25,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) a declaratory judgment that Bayer Defendants are liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Bayer Defendants' wrongdoing; (iv) disgorgement of profits; (v) attorneys' fees and costs;

(vi) prejudgment interest; (vii) punitive or exemplary damages according to proof; (viii) injunctive relief; and (ix) such other and further relief as this Court may deem just and proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY

379. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

380. Defendants failed to warn Plaintiffs and their physicians of the risk of serious defects and life altering complications described herein rendering the device defective and unreasonably dangerous.

381. Specifically, Defendants failed to:

a. report many of the roughly 16,000 complaints about Essure® to the FDA or the public;

b. report Essure®'s nonconformity with its performance specifications; and

c. update Essure®'s labeling or report to the FDA and the medical community their post-market information regarding complaints about Essure®.

382. Defendants also failed to revise their labeling to warn of the accurate rate of occurrence of adverse events based upon the post-market adverse event information available to them.

383. Plaintiffs' Essure® devices were defective at the time of sale and distribution and at the time they left the possession of Defendants in that Defendants failed to adequately warn of the risks of migration, perforation, penetration, device breakage, removal, chronic abnormal bleeding and pain, autoimmune response, and other injuries involved in the use of Essure®. The accurate rate of occurrence for these and other injuries associated with the use of Essure® were not readily recognizable to the ordinary consumer, including Plaintiffs and/or Plaintiffs' physicians.

384. The Essure® devices were defective and unreasonably dangerous due to inadequate warnings and/or instruction because Defendants knew or should have known that the products created a serious risk of migration, perforation, penetration, autoimmune response, and other harm to consumers, and Defendants failed to adequately warn consumers of said risks - including Plaintiffs and/or their healthcare physicians - in accordance with state law, including Missouri law.

385. The Essure® devices manufactured and sold by Defendants were defective and unreasonably dangerous due to inadequate warnings and instructions because Defendants knew or should have known

that Essure® created, among other things, a higher than expected risk for adverse events, and Defendants failed to adequately warn of those risks, to monitor those risks, report them, and update its labeling regarding such risks when the information became available.

386. At all relevant times, Plaintiffs' Essure® devices were prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

387. The Essure® devices manufactured, marketed, promoted, and sold by Defendants were expected to, and did, reach Plaintiffs without substantial change in the condition in which they were sold.

388. Despite the fact that Defendants knew or should have known that the use of Essure® was unreasonably dangerous and likely to place users at serious risks to their health, Defendants failed to monitor and warn of the defects, health hazards, and risks associated with Essure®.

389. Plaintiffs' Essure® devices were also defective at the time of sale and distribution, and at the time the devices left the possession of Defendants, in that the devices differed from Defendants' intended result and design specifications.

390. Defendants violated state law, including Missouri law, by placing the Essure® system into the stream of commerce in a defective and unreasonably dangerous condition.

391. The defects inherent in the Essure® devices were not readily recognizable to the ordinary consumer, including Plaintiffs and/or Plaintiffs' physicians.

392. At all relevant times, Plaintiffs' Essure® devices were prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

393. The Essure® devices manufactured, designed, promoted, marketed, and sold by Defendants were expected to, and did, reach Plaintiffs without substantial change in the condition in which they were sold.

394. Defendants knew that the Essure® devices would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

395. At all times relevant to this action, the dangerous propensities of Essure® were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to prescribe and implant Essure® for their patients.

396. Defendants knew that physicians and other healthcare providers began prescribing this product as a safe and effective contraceptive device despite its potential for serious, severe, and permanent side effects.

397. Defendants were required to provide adequate warnings to consumers and the medical community under federal and state law, including Missouri law, but failed to do so in a timely and responsible manner.

398. Had Defendants timely and adequately reported the adverse events to the FDA, there would have been effective warnings to physicians, including Plaintiffs' physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs and/or Plaintiffs' physicians, regarding the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

399. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, the FDA held a public hearing discussing the risks and benefits of the device and then required a black box warning and Patient Decision Checklist for Essure® that warns of many of the same injuries that Plaintiffs have experienced due to Essure®.

400. Defendants' delay in timely reporting their known complications prevented the Plaintiffs and their physicians from having updated information concerning the real life risks associated with the Essure® device. Had the Plaintiffs and their physicians received timely and adequate information of these serious risks and adverse events, they would not have agreed to the Essure® implant, nor would their physicians have recommended use of this product.

401. Further, because Defendants failed to follow specifications, regulations, and required Good Manufacturing Practices, Plaintiffs' Essure® coils became unpassivated, making it vulnerable to degradation, deterioration, leaching, breakage, and fragmentation.

402. Essure®, which was manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented defectively by Defendants, was a substantial contributing factor in bringing about Plaintiffs' injuries, which would not have occurred but for the use of Essure®.

403. The defective warnings were a substantial contributing factor in bringing about the injuries to

Plaintiffs that would not have occurred but for the use of Essure®.

404. As a proximate result and/or substantial factor of the Essure®'s defective condition at the time it was sold, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

405. By reason of the foregoing, Plaintiffs have been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

406. WHEREFORE, Plaintiffs pray for judgment against Bayer Defendants, jointly and severally, in an amount in excess of Twenty Five Thousand Dollars ($25,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) a declaratory judgment that Bayer Defendants are liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Bayer Defendants' wrongdoing; (iv) disgorgement of profits; (v) attorneys' fees and costs; (vi) prejudgment interest; (vii) punitive or exemplary damages according to proof; (viii) injunctive relief; and (ix) such other and further relief as this Court may deem just and proper.

THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

407. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

408. Defendants expressly warranted Essure® to be safe for use by the general public, including Plaintiffs and/or their healthcare providers.

409. Defendants also expressly warranted that Essure® was safer and more effective than other permanent methods of birth control, such as tubal ligation.

410. Defendants' express warranties disseminated through Conceptus's Essure® marketing strategy developed using Missouri physicians as described in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics," were specifically and expressly communicated to Plaintiffs

in such a manner that Plaintiffs understood and accepted them.

411. Defendants' affirmations of fact or promise and descriptions of Essure® disseminated through Conceptus's Essure® marketing strategy developed using Missouri physicians as described in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics," regarding Essure® created a basis of the bargain for Plaintiffs and/or their physicians.

412. At the time of making of the express warranties, Defendants had knowledge of the purpose for which Essure® was to be used and warranted the device to be in all respects fit, safe, effective, and proper for such purpose. Essure® was unaccompanied by adequate warnings of its dangerous propensities and lack of effectiveness that were either known or knowable to Defendants at the time of distribution and sale.

413. Defendants' breaches of their express warranties under state law parallel their violations of federal law; the Essure® CPMA specifically mandates, and state law, including Missouri law, independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws. The warranties developed through the marketing strategy Defendants created using Missouri physicians were untrue, inaccurate, misleading, and not consistent with applicable federal and state laws.

414. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendants, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws."

415. Plaintiffs and/or their healthcare providers reasonably relied upon the skill and judgment of Defendants, and upon said express warranties, in using Essure®. The warranties and representations developed through the marketing strategy Defendants created using Missouri physicians were untrue in that Essure® was unsafe and unsuited for the use for which it was intended.

416. As soon as the true nature of Essure® and the fact that the warranties and representations were false was ascertained, Defendants were on notice of the breach of said warranties.

417. As a proximate result of Defendants' warranties and Plaintiffs' and Plaintiffs' physicians' reliance on same, Plaintiffs have suffered and continue to suffer severe physical injuries, severe emotional

distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

418. WHEREFORE, Plaintiffs pray for judgment against Bayer Defendants, jointly and severally, in an amount in excess of Twenty Five Thousand Dollars ($25,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) a declaratory judgment that Bayer Defendants are liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Bayer Defendants' wrongdoing; (iv) disgorgement of profits; (v) attorneys' fees and costs; (vi) prejudgment interest; (vii) punitive or exemplary damages according to proof; (viii) injunctive relief; and (ix) such other and further relief as this Court may deem just and proper.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

419. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

420. At all relevant times, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and sold Essure®.

421. Prior to Plaintiffs' implantation of Essure®, Defendants impliedly warranted to Plaintiffs and Plaintiffs' health care providers that Essure® was of merchantable quality, reasonably fit for its intended purpose, and safe for the use for which it was intended.

422. Defendants also warranted that Essure® was safer and more effective than other permanent methods of birth control, such as tubal ligation.

423. At all relevant times, Plaintiffs used Essure® for the purpose and in the manner intended by Defendants.

424. At all relevant times, Essure® was not reasonably safe for its expected purpose, nor reasonably fit for the ordinary purpose for which it was sold and/or used and it did not meet the expectations for the performance of the product when used in a customary, usual and reasonably foreseeable manner.

425. Plaintiffs and/or their healthcare providers reasonably relied upon the skill and judgment of Defendants and upon said warranties in using Essure®.

426. Defendants' breaches of their implied warranties under state law parallel their violations of federal law; the Essure® CPMA specifically mandates, and state law, including Missouri law, independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

427. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendants, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws."

428. As soon as the true nature of Essure® and the fact that the warranties and representations were false was ascertained, Defendants were on notice of the breach of said warranties.

429. As a proximate and legal result of Defendants' breach of warranty, Plaintiffs were caused to suffer and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

430. WHEREFORE, Plaintiffs pray for judgment against Bayer Defendants, jointly and severally, in an amount in excess of Twenty Five Thousand Dollars ($25,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) a declaratory judgment that Bayer Defendants are liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Bayer Defendants' wrongdoing; (iv) disgorgement of profits; (v) attorneys' fees and costs; (vi) prejudgment interest; (vii) punitive or exemplary damages according to proof; (viii) injunctive relief; and (ix) such other and further relief as this Court may deem just and proper.

FIFTH CAUSE OF ACTION
FRAUD

431. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

432. At all times mentioned in this Petition, Defendants had the duty and obligation to disclose to Plaintiffs and/or their healthcare providers, the true facts concerning Essure®.

433. Defendants concealed material facts concerning Essure® from Plaintiffs, their physicians, and other healthcare providers, including but not limited to the following:

a. Defendants received and fraudulently concealed 16,047 complaints regarding Essure® in which pain was experienced by consumers. The FDA's Establishment Inspection Report on June 26, 2013 states: "the inspection found that the firm was not reporting as MDRs complaints in which their product migrated from the fallopian tube into the peritoneal cavity, the firm did not consider these complaints in their risk analysis for the design of their product, and the firm failed to document CAPA activities."

b. Defendants fraudulently concealed eight perforations which were caused by Essure® and which Defendants failed to disclose to Plaintiffs, Plaintiffs' healthcare providers, and the FDA. The FDA memorialized this concealment in its Investigative Report and Form 483 dated January 25, 2011, stating: "the firm had not properly evaluated eight complaints of peritoneal perforation for reporting to the FDA as an adverse event. Also, the firm's risk analysis did not include an evaluation of the risk associated with perforation of the peritoneal cavity."

c. On January 6, 2011, the FDA issued a violation to Defendants for not submitting timely MDR reports when it received information that reasonably suggested that Essure® "may have caused or contributed to a death or serious injury if the malfunction were to recur." This information included incidents regarding perforation of bowels, Essure® coils breaking into pieces, and Essure® coils migrating out of fallopian tubes. Defendants had notice of 168 perforations but only disclosed twenty-two to the FDA.

d. On January 6, 2011, the FDA cited Defendants for failing to document Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' design. In addition, Defendants' CAPA did not mention the non-conformity of materials used in Essure® or certain detachment failures, despite Defendants' knowledge of same.

434. As described above, Defendants made affirmative representations to Plaintiffs and/or their physicians before Essure® was implanted in Plaintiffs that Essure® was safe and effective - while

concealing the material facts set forth herein - with the intent or purpose that Plaintiffs, their physicians, and the healthcare industry would rely on them, leading to the use of Essure® by Plaintiffs. These affirmative representations made to Plaintiffs and/or their physicians were developed using a marketing strategy Defendants created using Missouri-based physicians.

435. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiffs and their physicians with the intent to defraud as alleged herein.

436. Defendants willfully deceived Plaintiffs, their healthcare providers, the medical community, and the public in general, by suggesting untrue facts about their product that they knew to be false or had no reasonable ground for believing to be true, and by concealing material information concerning Essure®, which Defendants had a duty to disclose.

437. At the time Essure® was manufactured, distributed, and sold to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiffs and their physicians. Defendants knew the true safety and effectiveness of Essure®, despite dispensing untrue facts to Plaintiffs through a marketing strategy created using Missouri-based physicians.

438. Neither Plaintiffs nor their healthcare providers were aware of the concealed and/or suppressed facts set forth herein. Had Plaintiffs and/or their healthcare providers been aware of those facts, they would not have purchased and used Essure®, and Plaintiffs would not have been injured as a result.

439. Plaintiffs and their physicians justifiably relied on and/or were induced by Defendants' intentional misrepresentations and/or concealment. Specifically, Plaintiffs would never have had the Essure® device implanted had they been aware that there were multiple reports of perforations of human cavities or that there had been 16,047 complaints regarding Essure®.

440. It is reasonable that Plaintiffs, their physicians, and the healthcare industry would rely on the statements of Defendants regarding whether Essure® was safe and effective because, as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

441. Defendants had a duty to warn Plaintiffs, their physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. Defendants also had a post-market duty to monitor, report, and update its labeling to show the true safety and risk parameters of the

device.

442. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiffs and their healthcare providers reasonably relied on Defendants' deception and, Plaintiffs were implanted with Essure® and subsequently sustained injuries and damages as described herein. Defendants' concealment was a substantial contributing factor in causing Plaintiffs' injuries.

443. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs seek punitive damages according to proof.

444. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

445. WHEREFORE, Plaintiffs pray for judgment against Bayer Defendants, jointly and severally, in an amount in excess of Twenty Five Thousand Dollars ($25,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) a declaratory judgment that Bayer Defendants are liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by the Defendants' wrongdoing; (iv) disgorgement of profits; (v) attorneys' fees and costs; (vi) prejudgment interest; (vii) punitive or exemplary damages according to proof; (viii) injunctive relief; and (ix) such other and further relief as this Court may deem just and proper.

REQUEST FOR PUNITIVE DAMAGES

446. Plaintiffs incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

447. At all times relevant herein, Defendants:

a. knew or should have known that Essure® was dangerous, defective, and ineffective;

b. concealed the dangers and health risks from Plaintiffs, physicians, other medical providers, the FDA, and the public at large;

c. attempted to misrepresent and did knowingly make misrepresentations to Plaintiffs, their physicians, hospitals, other medical providers, and the public in general, as previously

stated herein, as to the safety and efficacy of Essure®; and

d. with full knowledge of the health risks associated with Essure® and without adequate warnings of the same, manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, promoted, marketed, advertised, distributed, and sold Essure® for use.

448. Defendants, by and through its officers, directors, managing agents, authorized sales representatives, employees, and/or other agents who engaged in malicious, fraudulent, and oppressive conduct towards Plaintiffs and the public, acted with willful, wanton, conscious, and/or reckless disregard for the safety of Plaintiffs and the general public.

449. Defendants' misrepresentations include knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety of Essure®. Defendants' conduct was willful, wanton, and undertaken with a disregard for Plaintiffs' rights.

450. Notwithstanding the foregoing, Defendants continued to market Essure® to consumers, including Plaintiffs herein, without disclosing the risks.

451. Defendants knew of Essure®'s lack of warnings, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell Essure® without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm caused by Essure®.

452. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Essure® against its benefits.

453. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiffs suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiffs have become liable.

454. Defendants are liable jointly and/or severally for all general, special, and compensatory damages to which Plaintiffs are entitled by law. Plaintiffs seek actual and punitive damages from Defendants and allege that the conduct of Defendants was committed with knowing, conscious, careless, reckless, willful, wanton, deliberate, and grossly negligent disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate

to punish Defendants and deter them from similar conduct in the future.

AGENCY, ALTER EGO, JOINT VENTURE, AND CONSPIRACY

455. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

456. At all times herein mentioned, the Defendants were fully informed of the actions of their agents, representatives, contractors, and/or employees, and thereafter, no officer, director or managing agent of the Defendants repudiated those actions. The failure to repudiate constituted adoption and approval of said actions, and all Defendants and each of them thereby ratified those actions.

457. At all times mentioned herein, there existed (and still exists) a unity of interest between certain Defendants and other Defendants such that any individuality and separateness between the Defendants has ceased, and these Defendants are the alter egos of the other certain Defendants and exerted control over those Defendants. Defendant Bayer controlled its wholly owned subsidiaries to such a degree and in such a manner as to render them mere business units and to make them merely an agency, instrumentality, adjunct, or its alter ego. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege, sanction a fraud, and/or promote injustice.

458. Each of the Defendants herein expressly or impliedly agreed to work with and assist each other Defendant and unnamed parties toward the common purpose of promoting, recommending, and selling Essure® and toward the common interest of pecuniary gain.

459. Each of the Defendants performed the acts and omissions described herein in concert with the other Defendants and/or pursuant to a common design with the other Defendants.

460. Each of the Defendants knew the acts and omissions of the other Defendants herein constituted a breach of duty, and yet, each Defendant provided each other Defendant substantial assistance and/or encouragement.

461. Each of the Defendants provided substantial assistance to the other Defendants in accomplishing the intentional and tortious conduct described herein, and each Defendants' conduct, even when separately considered, constitutes a breach of duties owed to the Plaintiffs.

462. At all times herein mentioned, each of the Bayer Defendants was engaged in the business of

and/or was a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling Essure® device for use by the Plaintiffs and the Plaintiffs' physicians. As such, each of the Bayer Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for the Plaintiffs' damages.

463. The conduct of the Defendants caused the Plaintiffs' harm as described herein. The Plaintiffs' harm is not in any way attributable to any fault of the Plaintiffs or any third party or instrumentality. Uncertainty may exist regarding which Defendant and/or combination of Defendants caused the Plaintiffs' harm. The Defendants possess superior knowledge and information regarding which Defendant and/or combination of Defendants caused the Plaintiffs' injuries. Thus, the burden of proof is upon each Defendant to prove the Defendant did not cause the Plaintiffs' harm as described herein.

464. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

465. Due to the above, each cause of action is asserted against each Defendant herein, jointly and severally, even if each and every Defendant is not specifically identified as to each and every count.

EQUITABLE TOLLING/FRAUDULENT CONCEALMENT

466. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

467. Defendants' failure to report, document, or follow up on the known adverse event complaints, and concealment of adverse events, known defects, serious increased risks, dangers, and complications, constitute fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiffs herein.

468. Defendants are estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of Essure®, actively and intentionally concealed defects, suppressed reports and adverse information, failed to satisfy FDA and PMA requirements, failed to satisfy FDA and PMA notification requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and the Plaintiffs.

469. Instead, Defendant represented that Essure® was safer, more effective and the best alternative for permanent female sterilization despite their knowledge to the contrary.

470. At all relevant times, Defendants were under a continuing duty under federal law, the PMA and parallel state laws to disclose the true character, quality, and nature of the increased risks, adverse events, and dangers associated with Essure®.

471. As a result of Defendants' concealment of the true character, quality and nature of their product, they are estopped from relying on any statute of limitations defense.

472. Defendants furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects in Essure® and/or arising out of the use of Essure® and a continued and systematic failure to disclose and/or cover up such information from/to the Plaintiffs, Plaintiffs' physicians, and the public.

473. Defendants' acts and omissions, before, during, and/or after the act causing Plaintiffs' injury prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injury or cause thereof until recently.

474. Defendants' conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of the Plaintiffs.

DEMAND FOR JURY TRIAL

475. Each Plaintiff hereby demands a trial by jury as to all of their claims. Plaintiffs do not seek to have their claims tried jointly.

Dated: January 11, 2016

Respectfully Submitted,

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